

GLUCOWATCH[®]

OMATIC GLUCOSE BIOGRAPHER

and

AUTOSENSORS

PATIENT INFORMATION

CAUTION: U.S. federal law restricts the GlucoWatch[®] Biographer and AutoSensors to sale by or on the order of a physician.

WARNING: This device is not designed to replace your regular blood glucose meter. The GlucoWatch Biographer must be used with your blood glucose meter. Together, they can give you more information about glucose levels. You and your health care team may be able to use this information to manage your diabetes better.

IMPORTANT: Before you use the GlucoWatch Biographer, you must do 2 things:

- Complete an introductory training program provided by the manufacturer
- Read the *User's Guide* provided in the Starter Kit

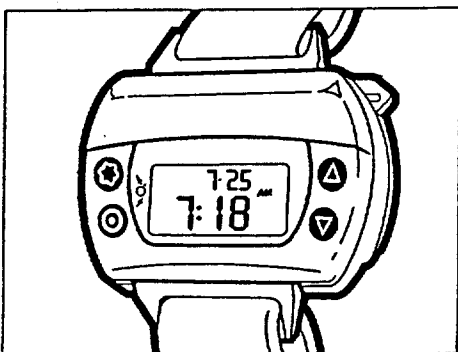
This product information sheet does not replace a complete reading of the *User's Guide*. If you have questions or need another copy of the *User's Guide*, please contact our Technical Services Department. The toll-free phone number is 1-866-GLWATCH.

What is the GlucoWatch Biographer?

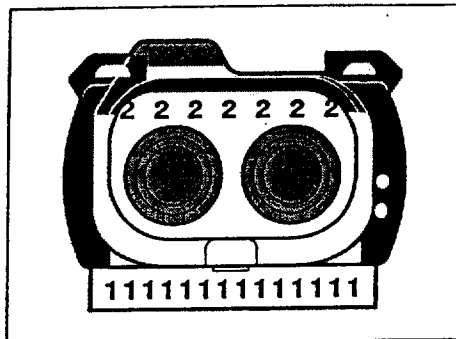
The GlucoWatch Biographer is a glucose monitoring device that is worn like a watch. Glucose readings are taken non-invasively through your skin. The Biographer provides automatic glucose readings every 20 minutes for up to 12 hours at a time.

The GlucoWatch[®] System consists of 2 main parts:

- The **GlucoWatch Biographer**: the watch-like device that measures glucose.



The **AutoSensor**: a plastic part that snaps into the biographer and sticks to your skin. Each AutoSensor provides up to 12 hours of readings. The AutoSensor must be replaced every time you wear the Biographer.



How does the GlucoWatch Biographer work?

An extremely low electric current pulls glucose through the skin. The glucose is collected in 2 gel discs that are part of the AutoSensor. Then an electrode in the AutoSensor measures the glucose.

- Each glucose reading is stored in memory and the readings can be viewed with the touch of a button
- The Biographer compares each 20-minute reading with high and low alert levels that you and your health care team select
- The Biographer sounds an alarm if glucose readings are:
 - Below the low alert level
 - Above the high alert level
 - Declining rapidly

What is the GlucoWatch Biographer used for?

The GlucoWatch Biographer detects trends and tracks patterns in your glucose levels. The Biographer can be used during your normal daily routine (while awake or asleep) at home or work. The frequent readings provided by the Biographer may help you manage your diabetes better.

The Biographer is meant for use by adults (age 18 and older) with diabetes. This is because, so far, the Biographer has been studied only in adults.

Can I use GlucoWatch Biographer readings in the same way I use finger-stick test results?

No. The Biographer is designed to help detect trends and patterns in your glucose levels. Most Biographer readings are similar to finger-stick test results taken around the same time. But some Biographer readings will differ from finger-stick tests. This difference can be important for proper treatment.

Managing diabetes means that you must make treatment decisions every day. Unfortunately, these decisions can sometimes cause problems. For example, too much insulin can result in low glucose levels and not enough can result in high glucose levels.

When it is time to make an important decision, the Biographer should not be used as a substitute for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

How can I use GlucoWatch Biographer readings to help manage my diabetes better?

The Biographer makes frequent glucose monitoring easier. With the Biographer you can see the trends and patterns in your glucose levels. For example, you can see your glucose levels rising after meals. This can help you and your health care team identify ways to improve your diabetes management.

The Biographer can also alert you when your glucose levels are too high or too low. These situations may be hard to identify with finger-stick testing alone.

Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

When should I wear the GlucoWatch Biographer?

You should discuss when to wear the GlucoWatch Biographer with your health care team. You and your health care team may decide that you should wear the Biographer:

- Every day, if you often have problems with high or low glucose levels
- At night, when changes in glucose levels are hard to detect
- On days when your normal routine is disrupted, for example, when you're especially busy or traveling
- When you need more information to help solve problems

You should change the place where you apply the Biographer to your skin each time you wear it. The low-level electric current used by the Biographer may cause some skin irritation (redness and/or itching) after use. These symptoms should disappear within a few days if you do not put the Biographer back on the same place on your arm. If irritation continues, talk to your doctor.

When do I need to use a regular blood glucose meter?

You must use a regular home blood glucose meter:

- To calibrate the GlucoWatch Biographer each time you use a new AutoSensor. To calibrate, you must do a blood glucose test and then enter the results into the Biographer. Everyone's skin is different. Your skin is also different from site to site and even day to day. Calibration adjusts the Biographer for the skin site you have chosen.
- To confirm the Biographer readings in certain circumstances that are described in the warnings section below.
- To monitor your blood glucose level as directed by your doctor. Since the Biographer is not designed to replace your regular blood glucose meter, never change how often you do finger-sticks without first talking with your doctor.

Important safety warnings about using the GlucoWatch Biographer

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The GlucoWatch Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular blood glucose meter to check the Biographer results.
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a sliding scale. If you use a sliding scale, be sure to confirm the Biographer reading with your regular blood glucose meter to

make sure you take the right amount of insulin.

- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.

Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a substitute for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

Precautions to make sure you use the GlucoWatch Biographer correctly

- Always do the calibration step carefully. Entering the right number is important for accurate results. Follow the instructions for using your regular blood glucose meter. If you question the reading from your regular meter that you plan to use for calibration, repeat the blood glucose test.
- Be sure to set the Low Glucose Alert level 20 to 30 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert at 80 or 90 mg/dL. Otherwise, the GlucoWatch Biographer may miss some low blood glucose events and the alarm will not sound.
- Always check the last few readings in the Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the Biographer readings with your regular blood glucose meter.
- Do not place the Biographer at any site where you have skin irritation left from a prior use. Also, do not place the Biographer on a scrape, cut, sunburn, or razor burn. Skin irritation may be worse than normal. Instead, use a different site on your arm.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use.
- Do not share your Biographer with another person. This will help prevent spreading infections.

How do I use the GlucoWatch Biographer?

Be sure to read the *User's Guide* included in your Starter Kit for full instructions. You should also refer to the video and *Quick Reference Guide* included in your Starter Kit. Here are the basic steps:

- Snap a new AutoSensor into the GlucoWatch Biographer.
- Put the Biographer onto your arm and press the Start button. This begins a 3-hour warm-up period.
- After the warm-up period, calibrate the Biographer using the result of a blood glucose test with your regular meter.
After calibration, the Biographer will give you a glucose reading every 20 minutes for up to 12 hours. After 12 hours the Biographer will stop glucose monitoring.
- The Biographer checks each reading for any sign of a technical problem that might cause a reading to be inaccurate. If a problem is detected, the reading is skipped. The word SKIP will appear on

the Biographer display, but monitoring will continue.

- Certain problems (for example, dislodging the Biographer from your skin) can cause the system to shut off glucose monitoring completely.

The **Troubleshooting** section of your *User's Guide* provides more details on what can cause a skipped reading or an unexpected shut off.

What else will I need to use the GlucoWatch Biographer?

In addition to the items included in your Starter Kit, you will need:

- A regular blood glucose meter to calibrate the GlucoWatch Biographer, plus the other supplies you normally use for testing
- An alcohol wipe to clean your skin before putting on the Biographer
- A razor to remove excess hair that may prevent good contact between the AutoSensor and your skin

What can I do about the skin irritation caused by the GlucoWatch Biographer?

Most people have mild to moderate skin irritation after wearing the GlucoWatch Biographer. Occasionally blisters may result from friction between the skin and the Biographer. People with sensitive skin may get more redness or itching. However, following a few simple steps can help reduce the amount of skin irritation you get.

- Rotate wearing sites on your arms
- Keep irritated skin clean and dry
- Avoid scratching irritated areas
- Protect irritated areas from the sun
- Use lotion on irritated skin after removing the Biographer

If skin irritation lasts for more than 1 week, consult a health care professional.

Care and storage of the AutoSensors

- Before use, AutoSensors should generally be stored in a refrigerator (2° to 8° C [36° to 46° F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25° C or 77° F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month.
- Avoid long periods of storage at high temperatures. Do not store the AutoSensors in your car.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use.
- Use an AutoSensor immediately after opening the pouch it comes in. Do not store AutoSensors in open pouches.
- Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but cloudy appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.
- Dispose of used AutoSensors the same way you get rid of used blood glucose test strips.

Limitations of the GlucoWatch Biographer

- It takes time for the GlucoWatch Biographer to collect and measure your glucose. As a result, each Biographer reading corresponds to blood glucose values from about 15 minutes earlier. This 15-minute lag-time can be important when your glucose levels are falling rapidly. Keep lag-time in mind as you select your Low Glucose Alert level.
- If you are perspiring, you may get skipped readings. After you stop perspiring the Biographer will usually begin monitoring again. Very high levels of perspiration may cause the Biographer to stop monitoring completely. The alarm will sound if perspiration causes a skipped reading or a shut off. Remember that perspiration can be one of the symptoms of low blood glucose.
- Bumping or jarring the Biographer may also cause skipped readings or a shut off.
- The Biographer alarm may be difficult to hear if there is a lot of background noise. The alarm may also be difficult to hear at night if:
 - You are a heavy sleeper
 - You have difficulty with your hearing
 - The Biographer is under a pillow or blanketThe alarm will stay on and beep faster and faster until you press a button to shut it off.
- Never immerse your Biographer in water. Your Biographer is splash resistant, not waterproof. This means you can wear it in the rain or while washing your hands. You should not wear the Biographer while showering, bathing, or swimming.
- The Biographer has been studied only in adults (age 18 and older). Studies have included over 1,400 uses of the Biographer by hundreds of people with diabetes. No change was seen in accuracy or skin irritation during the studies. No studies have yet been done for longer than 6 weeks.
- The Biographer readings may be affected by some hospital tests that use high electromagnetic equipment. This includes X rays and MRI tests.
- The medicines tolazamide or dopamine may affect the Biographer readings. Tolazamide is a pill sometimes used for type 2 diabetes. Dopamine is given by injection for heart failure or shock. Ask a member of your health care team if you are uncertain if you are taking either of these medications.

Target glucose values for people with diabetes

Your own target glucose values should be determined with your health care team. If your glucose readings are frequently too low or too high, consult your health care team.

Your regular blood glucose meter gives test results that are either:

- whole blood glucose values, or
- plasma glucose values

All meters use whole blood to begin the test. The difference comes with how the result is calculated. Check the instructions for your meter to find out what kind of values it gives.

The Biographer readings are based on the finger-stick test result you use to calibrate the Biographer. This means that if your meter gives whole blood glucose values, the Biographer readings will also be whole blood values. If your meter gives plasma glucose values, the Biographer readings will be plasma values.

Target glucose levels for people with diabetes depend on what type of result your meter and the Biographer provide. TABLE I below shows the general targets suggested by the American Diabetes Association.¹

| TABLE I | If your regular meter provides whole blood glucose values: | If your regular meter provides plasma glucose values: |
|---------------|--|---|
| Before meals: | 80-120 mg/dL | 90-130 mg/dL |
| At bedtime: | 100-140 mg/dL | 110-150 mg/dL |

Ensuring the accuracy of your Biographer readings

- The *User's Guide* includes directions for how to test your GlucoWatch Biographer to make sure it is working correctly. Two types of tests can be done: the System Check and the QC (Quality Control) Test.
- The System Check tests to make sure your Biographer is operating properly. Run a System Check before using your Biographer for the first time and then once before using the first AutoSensor from a new box. Also run a System Check if the Biographer is dropped or damaged in any way.
- The QC Test checks the AutoSensors. Conduct a QC Test if you suspect that the AutoSensors have been exposed to extreme temperatures. Also run a QC Test if you have trouble calibrating the Biographer or if you question a series of Biographer readings.

The *User's Guide* explains how to do these tests.

- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time.
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test.
- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier.

HEALTH CARE PROFESSIONAL INFORMATION

This section is meant for health care professionals. If you are a patient with diabetes, please read the Patient Information first. If you have questions about the Health Care Professional Information, ask a member of your health care team.

Health Care Professionals: Please read the Patient Information for the Warnings, Precautions, and Limitations. Patients must be able to use a standard blood glucose meter accurately before using the GlucoWatch Biographer. Each patient must complete an introductory training program (provided by the manufacturer) before using the device. In addition, some patients may need further training on how to use the Biographer. The training needs of each patient should be assessed by the health care professional before prescribing this device.

INTENDED USE

The GlucoWatch Biographer is a glucose monitoring device indicated for detecting trends and tracking patterns in glucose levels in adults (age 18 and older) with diabetes. This device is intended for use by patients at home and in health care facilities.

The GlucoWatch Biographer is indicated for use as an adjunctive device to supplement, not replace, information obtained from standard home glucose monitoring devices.

The Biographer is indicated for use in the detection and assessment of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments, which may minimize these excursions. Interpretation of Biographer results should be based on the trends and patterns seen with several sequential readings over time.

OTHER IMPORTANT INFORMATION

- The device is for prescription use only.
- The device provides supplemental information that is **not a replacement** for blood glucose results obtained from standard home glucose monitoring devices.
- Changes in insulin therapy should not be made based solely on the Biographer results. Interpretation of Biographer results should be based on the trends and patterns seen with several sequential readings over time.
- The Biographer works differently than standard blood glucose meters (see Testing Principle Section). As a result, individual Biographer readings can differ substantially from blood glucose measurements taken at approximately the same time. These individual differences can be somewhat unpredictable and should be taken into account when interpreting results (see Performance Characteristics Section).
- Performance of the device can vary from use to use (ie, day 1 versus day 2) as well as within an individual 12-hour monitoring period.
- Mild to moderate skin irritation occurs in many patients.
- Skipped readings and unexpected shut offs may occur due to excessive perspiration, jarring, or dislodging of the device from the skin.
- Performance of this device has been studied only in patients age 18 and older.

Patients should be advised of when and how often to use the Biographer. Decisions about how to use the Biographer in a patient's diabetes management program should take into account the patient's ability to operate the device correctly and to understand device limitations. The patient must also be willing to accept the mild to moderate skin irritation that can result from use of the Biographer.

The Biographer is appropriate for daytime and/or nighttime use on a routine, periodic, or situational basis.

- Routine use (ie, daily) should be considered for patients making frequent therapy adjustments based on glucose monitoring results and for patients subject to frequent problems with hypoglycemia and/or hyperglycemia
- Periodic use (ie, weekly) should be considered for patients with more stable glucose levels or simpler therapy regimens
- Situational use (ie, during a change in therapy) can be helpful in addressing specific treatment or educational issues with certain patients

The Biographer is designed to help your patients identify trends and patterns in their glucose levels. Biographer readings, although accurate most of the time, may occasionally differ significantly from finger-stick test results and therefore must be used with finger-stick blood testing. Using Biographer results solely could result in improper and potentially harmful treatment decisions.

In many instances, the Biographer is able to alert your patient to a hypo- or hyperglycemic episode. Remember, however, that Biographer results may occasionally differ significantly from finger-stick results, and that the magnitude of trending patterns may not always be registered by the Biographer. The Biographer should not be depended on as the sole source of information concerning these episodes.

INDIVIDUALIZATION OF TREATMENT

The decision to prescribe the GlucoWatch Biographer should take into consideration the motivation and knowledge level of the patient and the patient's ability to understand the Warnings, Precautions, and Limitations described in this Product Information Sheet.

Carefully review target glucose values and the planned treatment program with each patient before advising the patient on when and how often to use the Biographer. Any change in treatment based on the alert capabilities of the Biographer should take into account any hearing difficulties the patient may have and the possibility that the Biographer may not detect all episodes of hypoglycemia or hyperglycemia. A patient logbook is available to document the use plan and record results.

While routine daily use may be appropriate for some patients, other approaches might include the following:

- Use on days when the patient's normal routine is disrupted (for example, during particularly busy periods or while traveling)
- Frequent use during periods of dose adjustment or other therapy transitions and then periodic (perhaps weekly) use for detailed profiles of glucose levels
- Regular use for several days to detect underlying problems in patients with higher than expected hemoglobin A_{1c} results relative to the patient's standard blood glucose testing results
- Nighttime use to investigate the causes of nocturnal or fasting hypoglycemia or hyperglycemia
- Educational use to show patients the effects of different dietary choices and activity levels

GLUCOWATCH[®]

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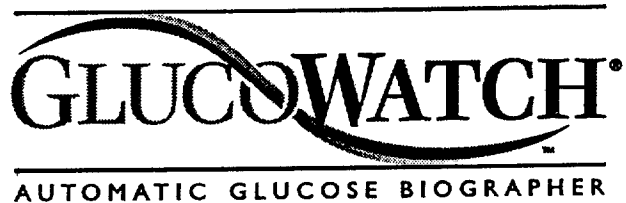
AUTOMATIC GLUCOSE BIOGRAPHER

USER'S GUIDE



An easy-to-follow guide to using your GlucoWatch Biographer

This pocket holds a Product Information sheet that contains important information, including warnings and precautions. A new Product Information sheet will be included inside each new box of GlucoWatch AutoSensors. Check each new Product Information sheet for new information about using your GlucoWatch Biographer.



User's Guide

Important Operating Instructions

Be sure to read this entire booklet. It provides complete instructions for operating and maintaining your GlucoWatch System.

For 24-hour product support, contact our Technical Services Department toll free at 1-866-GLWATCH.

*A new kind of freedom for
millions of people with diabetes*

Congratulations! By choosing the GlucoWatch® Automatic Glucose Biographer, you've taken an important step toward better diabetes management.

The GlucoWatch Automatic Glucose Biographer is a wrist-worn device intended to detect trends and track patterns in your glucose levels. The GlucoWatch Biographer is meant for use by adults (age 18 and older) with diabetes. It can be used during your normal daily routine at home and at work. The Biographer can be used even while you sleep. You should discuss when and how often to wear your GlucoWatch Biographer with your diabetes management team.

You must use a regular blood glucose meter to calibrate the Biographer each time you use a new AutoSensor. This means that you must enter the result from a finger-stick test into the Biographer every time you use the Biographer. You will also need a regular blood glucose meter to confirm the Biographer readings in certain circumstances.

The GlucoWatch Biographer is the first and only glucose monitoring system to provide 12 hours of frequent and automatic measurements of glucose levels. It has a unique alarm that automatically beeps to alert you if any of the automatic readings are above or below alert levels that you and your diabetes management team select. The alarm also sounds if your glucose level is falling rapidly and can work even while you sleep.

Frequent glucose monitoring plays an important role in controlling your diabetes. The Diabetes Control and Complications Trial (DCCT), a 10-year study of people with Type 1 diabetes, showed that frequent glucose monitoring, together with appropriate insulin adjustments, reduced long-term complications of diabetes such as nerve damage, eye damage, and kidney disease.¹

Even so, maintaining tight control isn't easy. One of the steps required for maintaining tight control is frequent testing of blood sugar levels.

Your GlucoWatch Biographer makes frequent glucose monitoring easier. It can measure glucose levels when you're asleep, on a long trip, stuck in traffic, or when a meeting runs longer than expected. Of course, there's some learning to do. Take it one step at a time. Before long you'll find it easy to use your GlucoWatch Biographer properly.

The information provided by your GlucoWatch Biographer, along with your finger-stick testing results, can help you and your health care team make specific changes in your treatment plan. With appropriate adjustments in diet, exercise, or medication, you can move toward improving and maintaining control of your diabetes.

Important warnings, precautions, and limitations of the GlucoWatch Biographer will be described throughout this *User's Guide*. Additional information about warnings and precautions is included on the Product Information sheet located in the pocket on the front cover of this *User's Guide*. A new Product Information sheet is also provided inside each new box of GlucoWatch AutoSensors. You should not make fundamental changes in your treatment program without consulting a member of your diabetes management team.

Your GlucoWatch Starter Kit, which includes this booklet, provides everything you need to know about the GlucoWatch Automatic Glucose Biographer. Watch the videotape for an easy-to-follow run-through on the use and operation of your GlucoWatch Biographer.

If you have any questions, please call our Technical Services Department toll free at 1-866-GLWATCH.

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INTRODUCTION



What your GlucoWatch Biographer can do for you

Your GlucoWatch Biographer gives you more information to help achieve better management of diabetes. You and your health care team can determine the best way to make your GlucoWatch Biographer a part of your current treatment plan. Using information about trends and patterns in glucose levels, along with finger-stick test results, you and your health care team can make adjustments to your medication, diet, exercise plan, and other factors that can help you maintain good control of your diabetes.

Early warnings

Thanks to advanced technology, your GlucoWatch Biographer has lots of practical features. One of the most valuable is its built-in "early warning system." Once you program it as described in this guide, your GlucoWatch Biographer is designed to alert you when your glucose levels may be approaching a danger zone.

What your GlucoWatch® Biographer can do for you (continued)

Your GlucoWatch Biographer lets you and your health care team set glucose alert levels for your individual needs.

Warnings:

- *Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The GlucoWatch Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular blood glucose meter to check the Biographer results.*
- *Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a "sliding scale." If you use a sliding scale, be sure to confirm the Biographer result with your regular blood glucose meter to make sure you take the right amount of insulin.*
- *Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.*
- *Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a "substitute" for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.*

Precautions:

- *Always check the last few readings in the Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the Biographer readings with your regular blood glucose meter.*
- *Be sure to set the Low Glucose Alert level 20 to 30 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert at 80 or 90 mg/dL. Otherwise, the GlucoWatch Biographer may miss some low blood glucose events and the alarm will not sound.*

*Measures your glucose when you can't
(or don't want to)*

After a 3-hour warm-up period and a finger-stick, your GlucoWatch Biographer is ready to go to work. Remember, after the warm-up, you can wear it for 12 hours at a stretch. Day or night, your GlucoWatch Biographer stands guard while you focus on other things like taking a long walk, finishing a project at work, or just catching up on your sleep.

How the GlucoWatch® Biographer works

Here's how the GlucoWatch Biographer works:

- The Biographer takes readings every 20 minutes for up to 12 hours
- The Biographer uses an extremely low electric current to pull glucose through the skin (this is called reverse iontophoresis) and into 2 gel collection discs
- The collected glucose triggers a chemical reaction within the gel that produces an electronic signal
- An electrode measures the signal, then the electronics of the Biographer convert the signal into the equivalent of a standard finger-stick glucose reading
- The Biographer compares each 20-minute reading with high and low alert levels that you and your health care team select

The GlucoWatch Biographer sounds an alarm if glucose readings are:

- ⊕ below the low alert level
- ⊕ above the high alert level
- ⊕ declining rapidly

The high and low alert levels should be worked out with your health care team. Once you program the alert levels, the alarm will sound if your automatic glucose readings reach or go beyond the levels you've chosen.

Precaution:

Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

The GlucoWatch System consists of 2 main parts:

- The GlucoWatch Biographer
- A single-use AutoSensor that provides up to 12 hours of readings

If you would like to know more technical details about how your GlucoWatch Biographer works, see the **Testing principle** section on page 10.8.

Understanding the lag-time concept

As you learned earlier, the GlucoWatch Biographer automatically monitors your glucose level every 20 minutes for up to 12 hours.

It takes time for the GlucoWatch Biographer to collect and measure your glucose. As a result, each Biographer reading corresponds to a blood glucose value from about 15 minutes earlier. This 15-minute "lag-time" can be important when your glucose levels are falling rapidly. Keep "lag-time" in mind as you select your Low Glucose Alert level.

Ensuring that the Biographer functions correctly

The GlucoWatch Biographer uses advanced technology to help ensure accurate glucose readings. However, there are a number of things you must do so that the Biographer functions correctly.

As outlined in this *User's Guide*, you must calibrate the Biographer before each 12-hour monitoring period. To do this, you must use a regular blood glucose meter. Carefully follow the instructions provided with the regular blood glucose meter. To help ensure accurate readings from your Biographer, the GlucoWatch *User's Guide* also explains how and when to conduct a System Check and a Quality Control Test.

The GlucoWatch Biographer automatically analyzes each glucose reading for potential problems. If a problem is identified, the glucose reading is "skipped" and the word **SKIP** appears on the Biographer display. Severe problems can cause the Biographer to discontinue glucose monitoring. Review the **Troubleshooting** section of this *User's Guide* for more details (see pages 9.1-9.8).

THE BASICS

THE BASICS



What's in your Starter Kit?

Check to make sure you have the following:

- 1 GlucoWatch Biographer
- 1 System Check Sensor (already in place on back of the Biographer)
- 2 nickel metal hydride (Ni-MH) AAA batteries
- 1 Ni-MH battery charger with adapter plug
- 2 watchbands (one already attached to the Biographer)
- 1 AutoSensor Press
- 1 instructional videotape
- 1 *Quick Reference Guide*
- 1 Personal Glucose Biography

Charging the batteries

Before using your GlucoWatch® Biographer for the first time, you must charge the Ni-MH batteries in the battery charger. This takes 3 hours, so you will have plenty of time to read through this manual and watch the video included in your Starter Kit. **You will need one freshly charged battery each time you put on your GlucoWatch Biographer.**

Caution:

Do not attempt to charge any other type of battery in your charger. It could be dangerous if you do. The charger is designed for use with Ni-MH batteries only.

The Ni-MH battery:

- Provides the primary power source for the GlucoWatch Biographer
- Recharges the internal lithium battery (it provides backup power)

For more information about the life of your Ni-MH batteries and backup power for your GlucoWatch Biographer, see page 8.1.



Tip: If you need more Ni-MH batteries, call Technical Services at 1-866-GLWATCH for assistance.

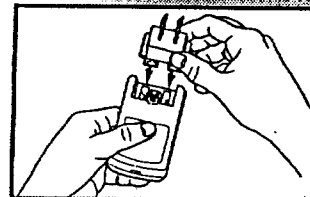
Follow these simple steps to charge the batteries:

Step 1: Attach the adapter plug to the charger.

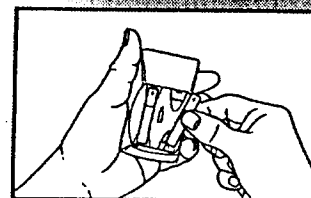
Step 2: Place the batteries in the battery slots of the charger. (Follow the diagram on the charger so that the batteries are inserted correctly.)

Step 3: Plug the charger directly into a convenient wall outlet.

The batteries should be fully charged in 3 hours. Each slot in the charger has a red LED cell to indicate the status of the battery.



Step 1



Step 2

| Type of LED signal | This means that |
|------------------------|---|
| Solid light | The battery is charging |
| Rapidly flashing light | The battery was placed in upside down or cannot be charged anymore and needs to be replaced |
| Slowly flashing light | The battery is ready for use in the GlucoWatch Biographer |

Caution:

Do not use an extension cord with your charger.

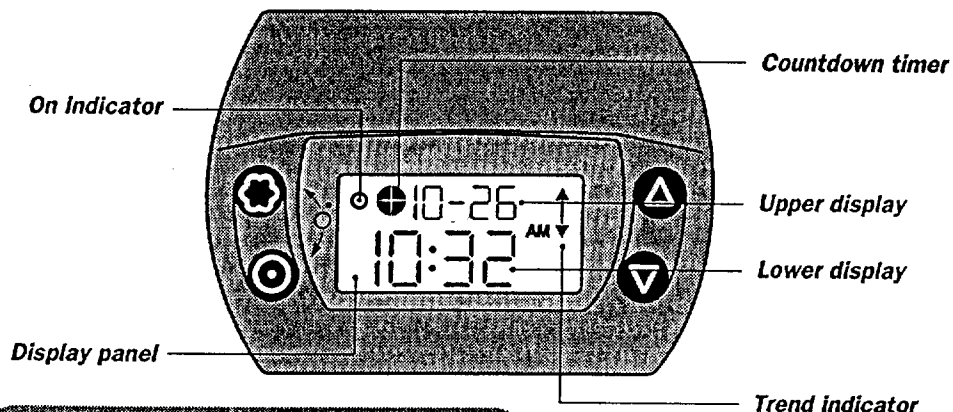
Note: The charger will not charge batteries that are below 41°F or above 113°F (below 5°C or above 45°C). The battery charger will measure battery temperature and start charging only when the batteries are within this range.

The charger must be used indoors only and protected from moisture. Periodically clean the battery contacts with a clean, dry cloth. Do not use any solvents or chemicals on the battery contacts.

The front of your Biographer

Study the following diagrams to become familiar with your GlucoWatch® Biographer.

Note: The On indicator, Trend indicator, and Countdown timer will only be displayed in certain circumstances.



Display panel
includes 2 displays of information,
the upper display and the lower display

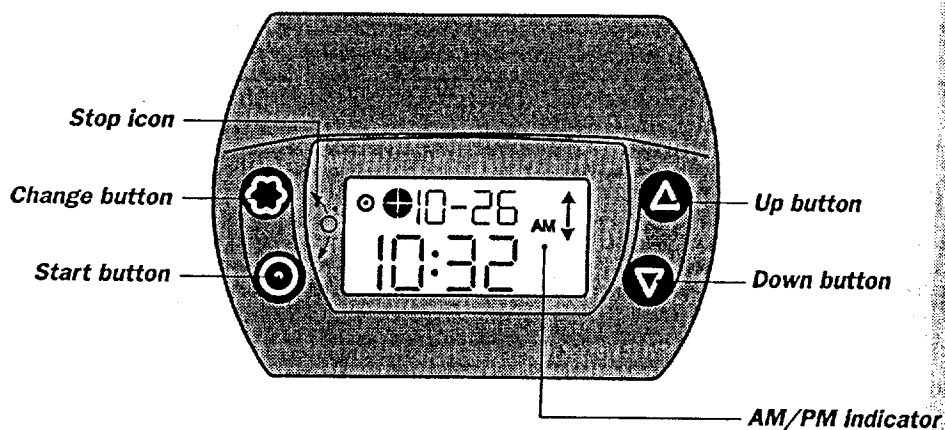
On indicator: Displays during the warm-up and 12-hour monitoring periods. Also displays during the System Check and QC Test.

Trend indicator: If the current reading is higher or lower than the previous reading by a specified amount, an up or down arrow displays along with the glucose result.

Countdown timer: Displays only after the Biographer has been successfully calibrated. Shows the time remaining before the next glucose reading.

Time to next reading:

- ⊕ 15 to 20 minutes
- ↗ 10 to 15 minutes
- 5 to 10 minutes
- ▴ 5 minutes or less



AM/PM Indicator: Displays unless 24-hour clock is selected.

Function buttons

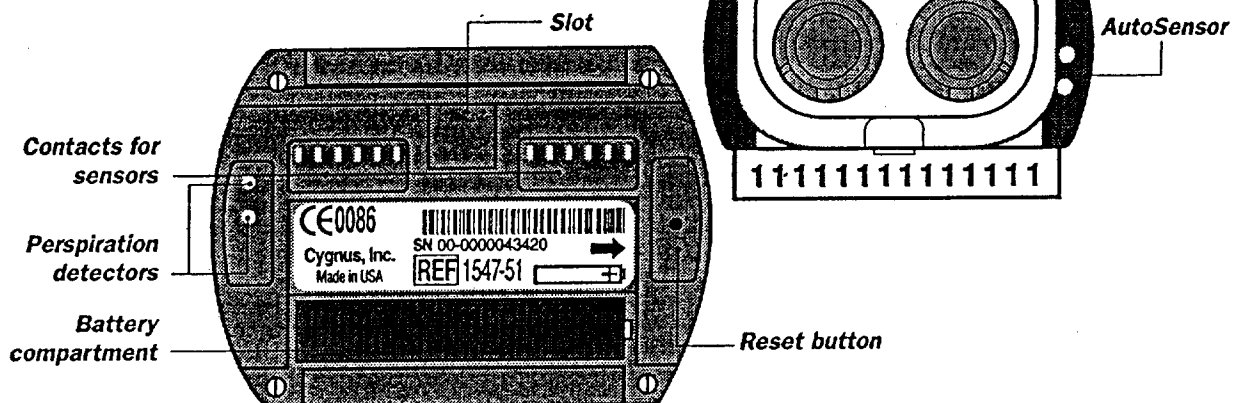
provide options for programming screen settings

- ⊗ **Change button:** Press and **hold** to set functions; press to turn off alarms.
- ⊙ **Start button:** Turns on glucose monitoring; confirms choice of options; returns to time/date display.
- ▲ **Up and ▼ Down buttons:** Scroll through glucose readings in memory or through functions.

To turn glucose monitoring off, press both the ⊙ Start AND ⊗ Change buttons at the same time.

The ⏏ Stop icon on the lens reminds you to press both the ⊗ Change and ⊙ Start buttons to shut off monitoring.

The back of your Biographer

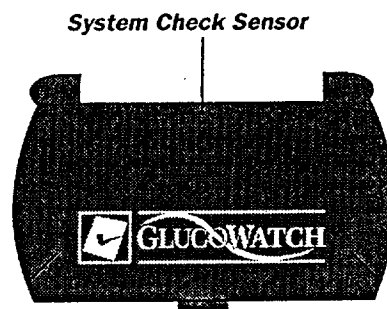


System Check Sensor: This is in place on the back of the GlucoWatch® Biographer when you get it, but must be removed to insert the AutoSensor. Put the System Check Sensor back in place when:

- Not wearing the Biographer
- Running a System Check (more on page 3.1)

Important: Do not discard!

You will need the System Check Sensor to test the electronics of the Biographer.



AutoSensor: Replace each time you wear your Biographer (more on pages 3.2 and 3.3).

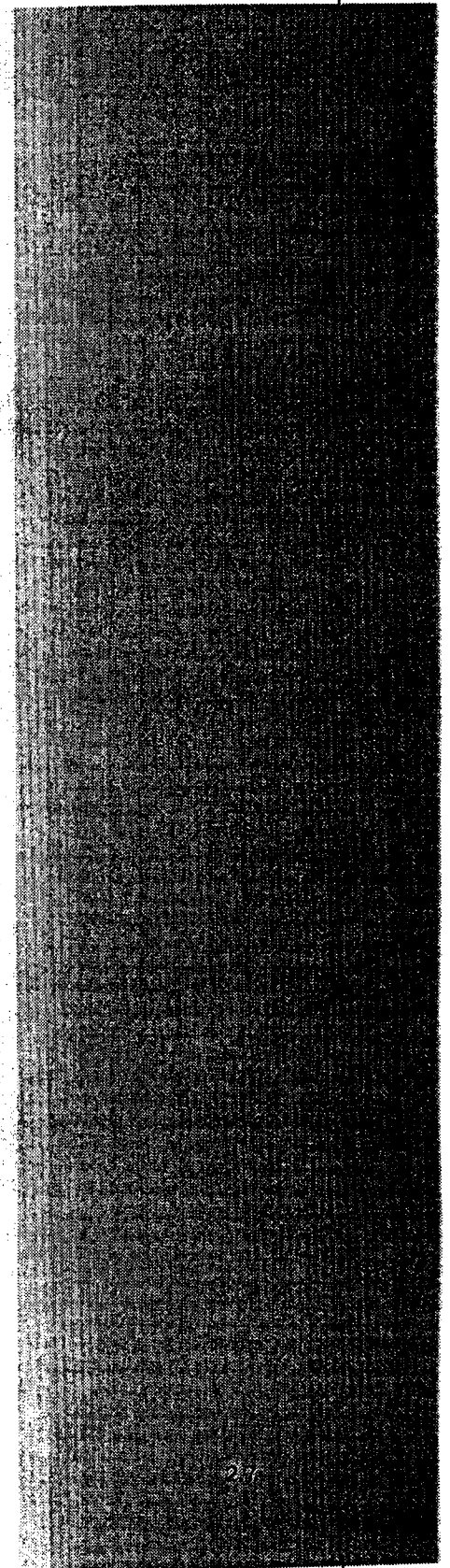
Battery compartment: Holds the rechargeable Ni-MH battery.

Perspiration detector: Measures perspiration (sweat)—too much sweat can cause skipped glucose readings, triggering the alarm and skip message (more on page 9.2).

Reset button: Resets the Biographer when the batteries (both main and backup) have run down.

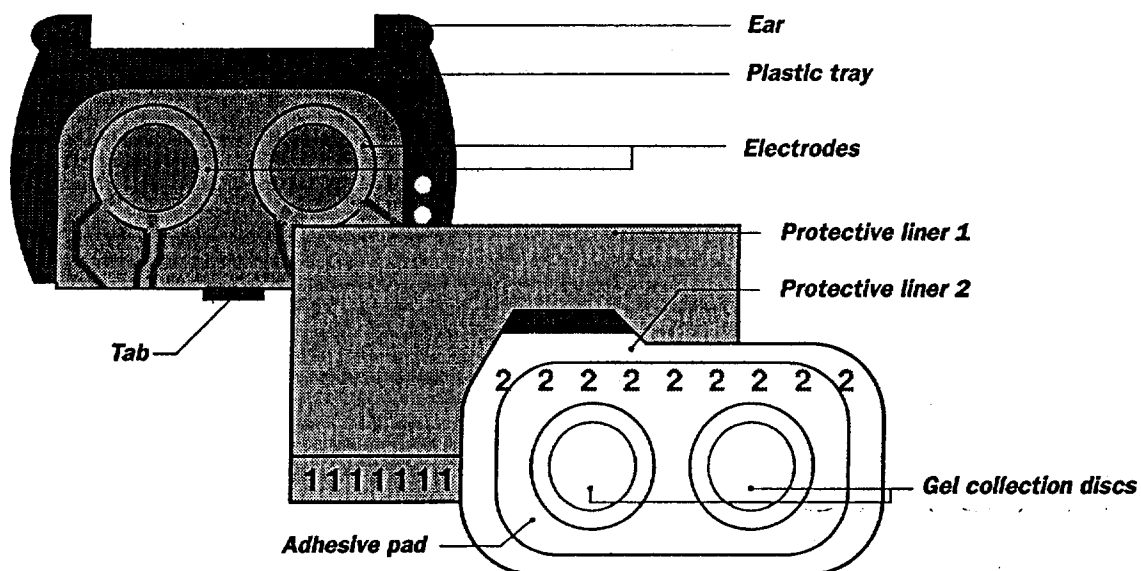
Contacts for sensors: Provide electrical connection to the sensors.

Slot: Connection point for the AutoSensor and System Check Sensor.



A look at the AutoSensor

Use a new AutoSensor each time you wear the GlucoWatch® Biographer.



Plastic tray: Holds electrodes and adhesive pad. The ears and tab on the plastic tray help you snap the AutoSensor into the GlucoWatch Biographer.

Electrodes: Send tiny electric currents into the skin that pull glucose through the skin and into a gel collection disc. The glucose interacts with enzymes in the gel and produces an electronic signal. The electrodes then measure the signal that is produced and the Biographer converts it into a blood glucose value.

Adhesive pad: Contains glucose collection discs in an adhesive plastic holder with protective liners.

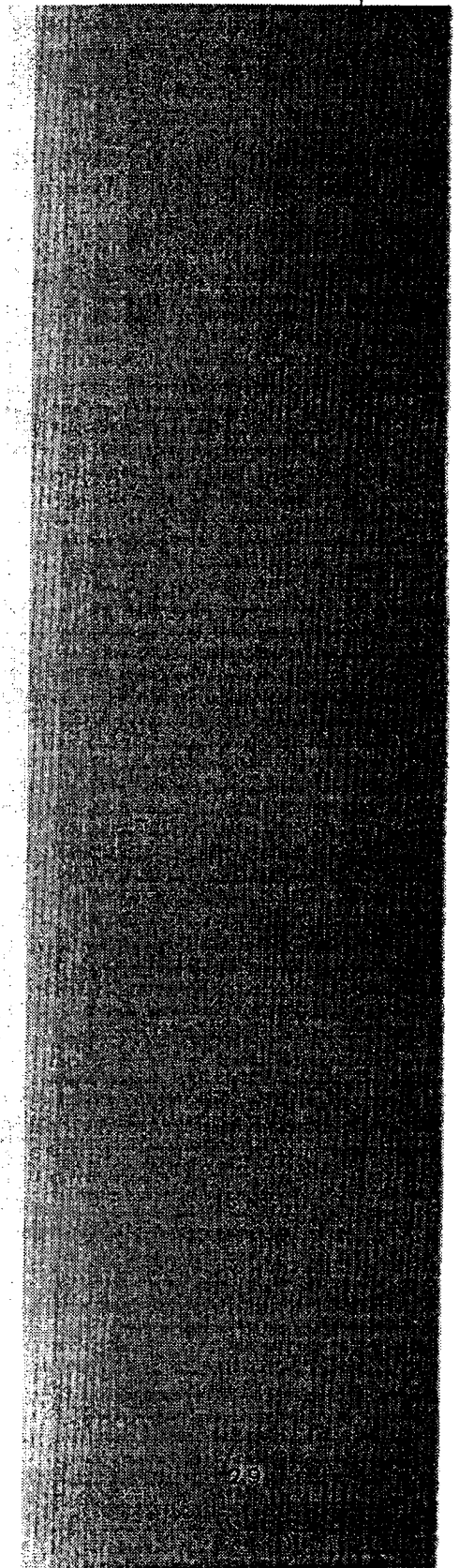
Protective liner 1: In between the electrodes and the adhesive pad. Pulls out so pad sticks to electrode surface.

Protective liner 2: On the top of the adhesive pad. Peels off so the AutoSensor sticks to your wrist or forearm.

Gel collection discs: Collect glucose and store enzymes that produce the chemical reactions needed to obtain glucose readings.

Caution:

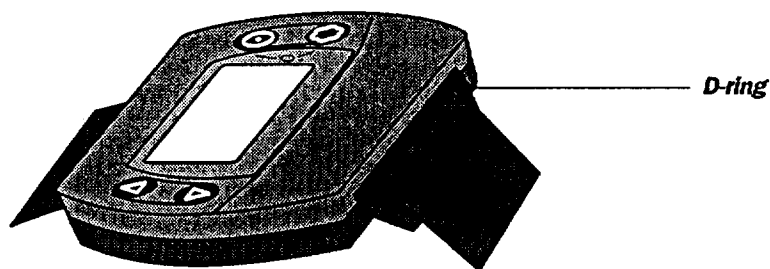
- Don't touch the surface with your fingers or other objects after protective liner 2 is removed
- Before use, AutoSensors should generally be stored in a refrigerator (2°C to 8°C [36°F to 46°F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25°C or 77°F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month
- Use AutoSensors immediately after opening the pouch. Do not store AutoSensors in open pouches
- Do not use an expired AutoSensor. Check the expiration date on the package label before use
- Check the gel collection discs for any spots or areas of different color. The gel collection discs should have a uniform but "cloudy" appearance. The gel collection discs are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration



Changing the watchband

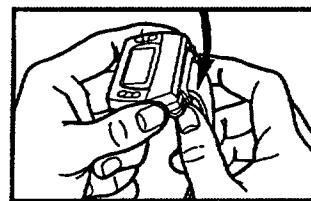
You may need to change the band on your GlucoWatch® Biographer, depending on the size of your wrist or where you position it on your forearm. (You will need to change wearing sites daily; see page 3.4 for details.)

A standard-size band comes attached to your Biographer. If this band does not fit, you can replace it with the additional watchband that is included in your Starter Kit. Read on to learn how to change the band.

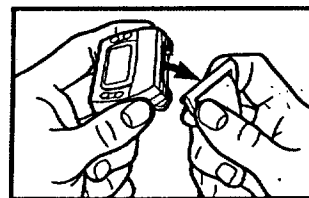


First, disconnect the band that's in place.

- Step 1:** Hold the GlucoWatch Biographer with the band at a right angle to the watch face.
- Step 2:** Press your thumb on the outside of the D-ring and your index finger on the inside.
- Step 3:** Rotate your thumb and finger in a clockwise motion to snap the band off the Biographer. This may require a lot of force. (Don't worry about breaking the plastic D-ring.)



Step 1

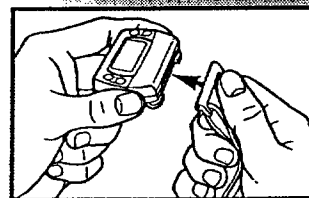
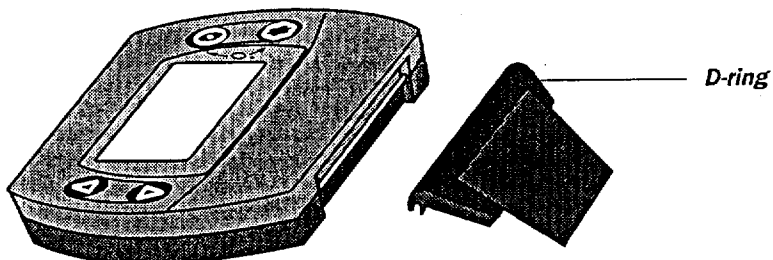


Steps 2 and 3

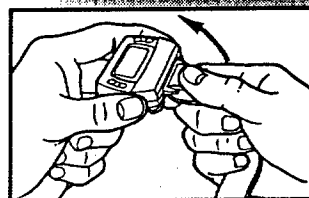
Then, attach the new band.

Step 1: Place the groove in the plastic D-ring over the metal rod on the Biographer with the band pointing downward.

Step 2: Rotate the D-ring upwards until you hear it snap in place. It should now be firmly attached.



Step 1



Step 2



Tip: To obtain a special-length watchband

- Call 1-866-GLWATCH for assistance in obtaining a special-length band if neither of the provided bands fits your arm

Practice putting on your Biographer and fastening the band

It's a good idea to practice putting on your GlucoWatch® Biographer and fastening the band ahead of time. Practice **before** you attach an AutoSensor to the Biographer.

Step 1: Insert the System Check Sensor in the back of your Biographer.

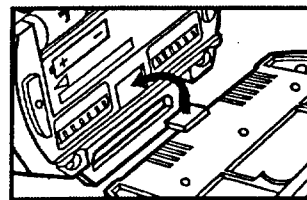
- Place the tab into the slot
- Snap the ears down onto the Biographer

Step 2: Carefully position the Biographer approximately 2 inches from your wrist.

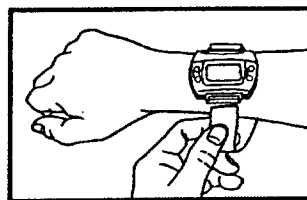
Step 3: Feed the strap through the D-ring.

Step 4: Pull the strap to tighten the band.

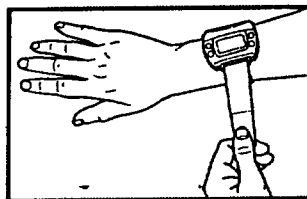
Step 5: Join the 2 Velcro® pieces together to fasten.



Step 1



Step 3



Step 4

Velcro® is a registered trademark of Velcro Industries B.V.

Inserting a battery into the Biographer

You will need to insert 1 freshly charged Ni-MH AAA battery into your GlucoWatch Biographer for each 12-hour glucose monitoring period. The procedure for inserting a battery is simple:

- Step 1:** Remove the System Check Sensor or AutoSensor by lifting the 2 ears on either side.
- Step 2:** Put a freshly charged Ni-MH battery in the battery compartment. Make sure the orientation of the battery matches the drawing on the label.



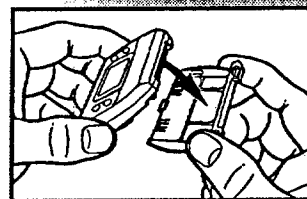
Tip: To remove the battery

- Press gently on either end of the battery. The other end will pop up so that you can pick up the battery and remove it.

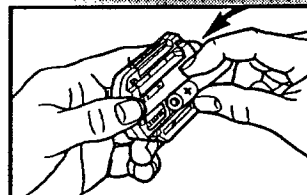
Caution:

Do not touch the battery compartment connectors with your fingers or any other object. You may bend or break the connectors that hold the battery in place.

Note: Immediately after putting in a new battery, the lower display may show a code beginning with M followed by a number. This indicates a problem with the Biographer's memory. See page 9.8 for an explanation of these codes or contact Technical Services toll free at 1-866-GLWATCH.



Step 1



Step 2

Setting the time and date

(A) Getting to the time and date screen

Step 1: Put in a Ni-MH battery and then replace the System Check Sensor so the battery doesn't fall out.


Step 2: You will now see the time and date screen with time on the lower display and date on the upper display.


(B) Setting the current time and date



To set the current time and date:


Step 1: Start at the time and date screen.


Note: The 4 numbers on the lower display may be flashing if you have pressed the reset button or put a battery into the Biographer for the first time.



Step 2: Press and hold the  Change button until you see the number at the far right flashing.

Step 3: Release the  Change button.

Step 4: Press the  or  button to select the correct number for the minutes.

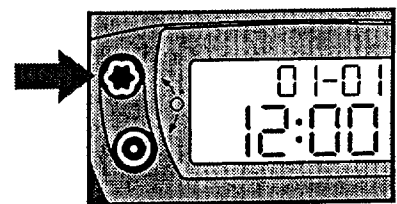
Step 5: Press the  Change button until you see the second number from the right flashing. Select the correct number to finish the minutes.

Step 6: Repeat the process until you have entered the correct hour. Press the  Change button.

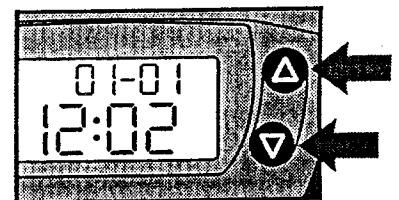
Step 7: You will now be prompted to enter the year, even though the year will not normally be displayed. Press the  or  button to select the correct year.

Example:

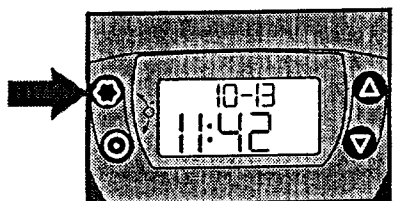
To change the time and date from 12:00 on Jan. 1 to 11:42 on Oct. 13:



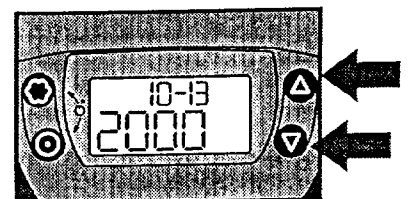
Step (B) 2



Step (B) 4








Steps (B) 5 and (B) 6



Step (B) 7

(B) Setting the current time and date (continued)

Step 8: Press the  Change button. You will now be prompted to enter the **month** and **day**. Press the  or  button to select the correct month and day.




Step 9: Check to make sure you entered the correct numbers. If you notice an error at this point, simply continue to press the  Change button until the digit you want to correct flashes. Press the  Start button to start the clock.

It's important to set an accurate time and date.

The GlucoWatch® Biographer stores the time and date for each glucose measurement taken. While the monitoring function is turned on, you cannot change the time and date.



Tip: For fast entry of time and date

- Press and **hold** the  Change button until the far right digit flashes
- Simply press and hold the  or  button. The GlucoWatch Biographer will scroll through numbers at high speed and you can enter the digit you want
- When you follow this procedure, the Biographer automatically moves from the right digit to the left digit so you can enter the next number in a sequence

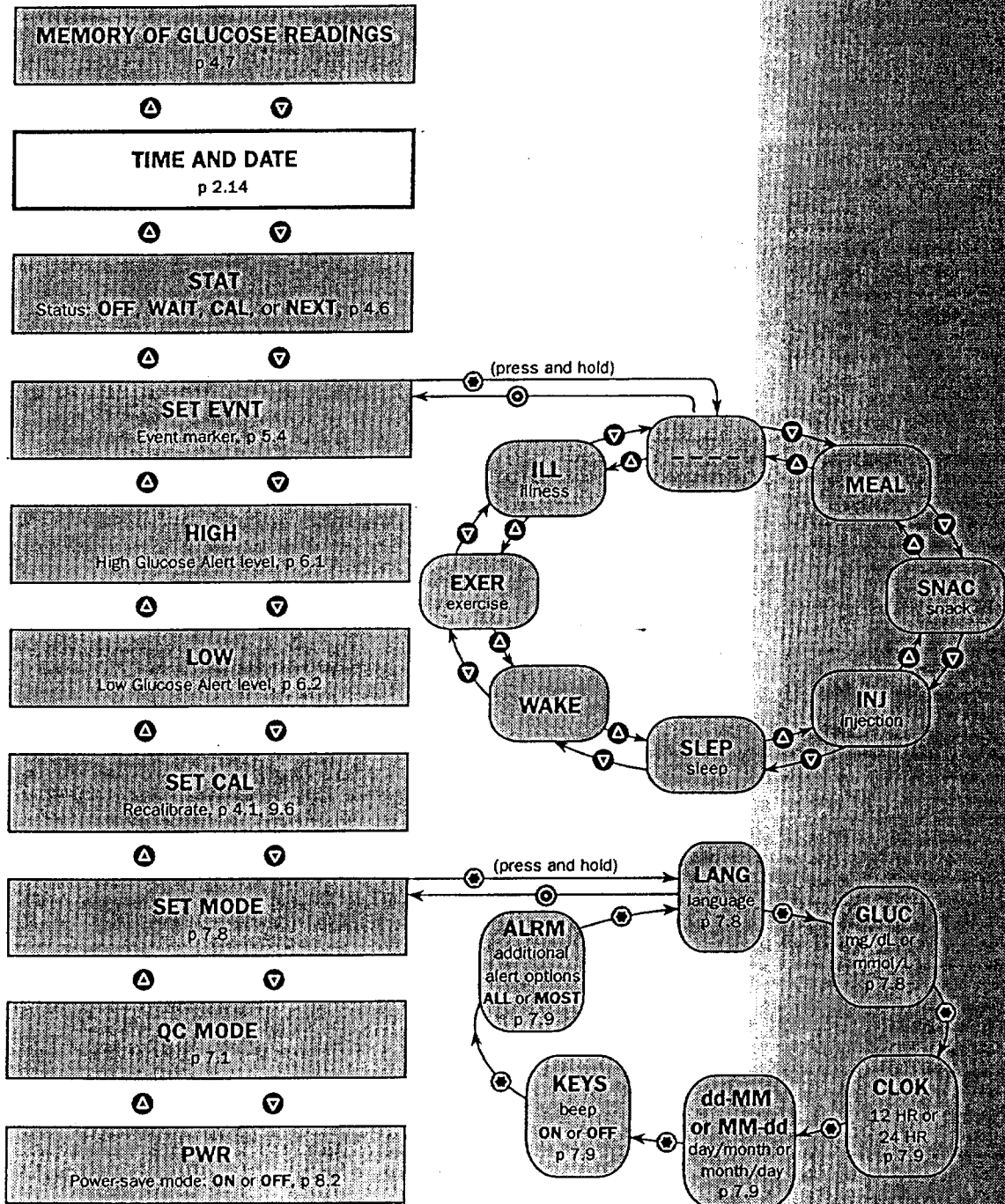
A map of the GlucoWatch® Biographer displays

In the next few chapters you'll be learning about all the functions of your GlucoWatch Biographer. You can reach most of the screens you want by simply pressing the ▲ or ▼ buttons repeatedly. In case you get lost, simply refer to the map of the operating system on the next page to determine where to go next.



Tip: To return to the time and date screen at any point

- Press the Ⓢ Start button and the time and date display will reappear
- OR
- Don't press any buttons for 30 seconds. In most situations, the time and date display will reappear automatically



BEFORE MONITORING

BEFORE MONITORING

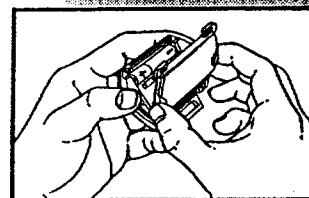
GLUCOWATCH[®]

AUTOMATIC GLUCOSE BIOGRAPHER

Running a System Check

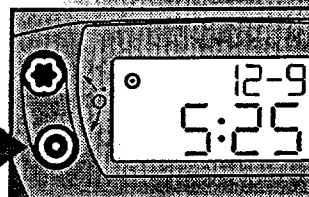
Your Starter Kit includes a special System Check Sensor to make sure that your GlucoWatch Biographer is operating properly. Be sure to run a System Check before using your GlucoWatch Biographer for the first time and then once before using the first AutoSensor from a new box. You should also run a System Check if the Biographer is dropped or damaged in any way. Here's how:

Step 1: Connect the System Check Sensor to the GlucoWatch Biographer. (You must have a charged Ni-MH battery in place.) Make sure you're using the System Check Sensor and not an AutoSensor.



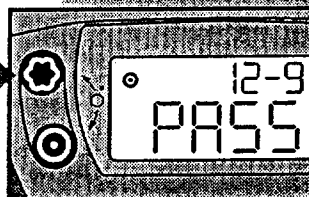
Step 1

Step 2: Press and hold the Ⓢ Start button for a few seconds until the Ⓢ On indicator appears on the display and you hear 2 beeps. The System Check will take about 10 seconds to complete.



Step 2

Step 3: At the end of the test, the alarm will sound and the lower display will show either **PASS** or **FAIL**. Press the Ⓢ Change button to confirm that you have heard the alarm.



Step 3

Step 4: If the display shows **PASS**, press the Ⓢ Start button to return to the time and date display. If the display shows **FAIL**, the System Check Sensor may not have been seated properly in the Biographer or the Biographer may be damaged. You may run another System Check (press the Ⓢ Start button to return to the time and date display) or call Technical Services for assistance.

The System Check Sensor should be able to be used many times. If the System Check Sensor is lost or damaged, call Technical Services at 1-866-GLWATCH for assistance.

Getting the Biographer ready for monitoring

Make sure the watchband is attached and a new Ni-MH AAA battery is securely in position. Remove the System Check Sensor.

Removing the AutoSensor from the pouch

Step 1: Follow the instructions printed on the label and cut open the pouch.

Step 2: Handling the AutoSensor by the ears, remove it from the pouch.

Caution :

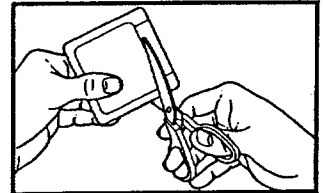
Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but "cloudy" appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.

Using the AutoSensor Press

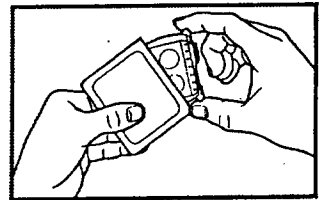
Using the AutoSensor Press is a critical step in obtaining accurate readings. Proper use of the Press helps ensure that the gel collection discs in the adhesive pad are firmly pressed onto the electrodes.

Step 1: Open the lid of the AutoSensor Press. Place the AutoSensor—**adhesive pad side up**—into the Press. There are 2 pegs in the Press that fit through the holes in the AutoSensor.

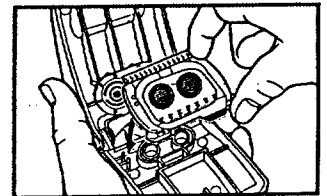
To remove the AutoSensor



Step 1



Step 2



Step 1

Using the AutoSensor Press (continued)

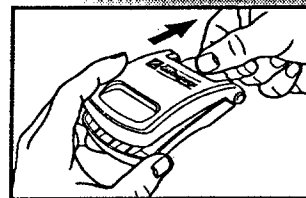
- Step 2:** Gently bring the lid of the AutoSensor Press down. Holding the AutoSensor Press by its sides, remove protective liner 1 on the AutoSensor by pulling the tab labeled with 1s through the opening at the hinged end of the Press. Discard the liner.
- Step 3:** Firmly close the Press so that the lid and the base touch. Hold closed for 10 seconds.
- Step 4:** Open the lid of the Press and remove the AutoSensor.

Caution:

Do not skip these important directions. Be sure to use the AutoSensor Press every time you use a new AutoSensor. Skipping this step may cause faulty readings. Do not directly press the adhesive pad onto the electrodes with your fingers.

Connecting the AutoSensor

- Step 1:** Remove the System Check Sensor if you have not already done so.
- Step 2:** Place the tab of the AutoSensor into the slot on the back of the GlucoWatch® Biographer.
- Step 3:** Holding the AutoSensor with your thumb and forefinger, snap it into place. A "click" lets you know the AutoSensor is properly seated.

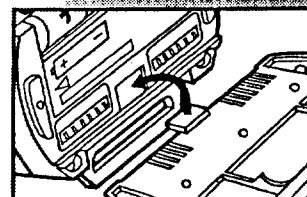


Step 2

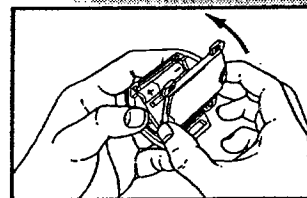


Step 3

To connect the AutoSensor



Step 2



Step 3

Choosing a wearing site for your Biographer

Feel free to wear the GlucoWatch® Biographer on either wrist or your inner or outer forearm. Make sure that the appropriately sized watchband is attached to the Biographer. Your Starter Kit includes 2 bands—one size should be right for you.



Tip: To ensure firm contact between your skin and the GlucoWatch Biographer, your skin must be

- Unbroken—no cuts, scrapes, sunburn, or razor burn
- Clean and dry—no lotions, perfumes, or medications
- Free of excess hair—important for firm contact of AutoSensor with skin

You may want to wear the Biographer on the inner surface of your arm, where there is less hair to remove. If you are planning to wear the Biographer over several days, consider shaving the whole forearm at once to avoid a “patchy” look as you change wearing sites.

It's best to remove hair at least 24 hours before placing the Biographer.

To minimize skin irritation, do not shave the site and apply the Biographer on the same day. An electric razor may be less irritating than a traditional razor.

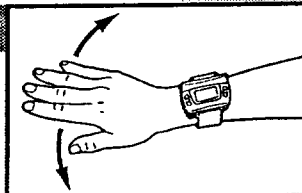
Caution: Each time you wear the GlucoWatch Biographer

- Choose a different place on your wrist or forearm.
- Make sure there is no irritation remaining from previous wearings. It generally takes about a week for skin to recover from the effects of low-level current. (For details on managing skin irritation resulting from wearing the Biographer, see page 10.2).
- Make sure your Biographer is never immersed in water; the Biographer is splash-resistant but not waterproof.

Make sure you are comfortable and your hands can move freely

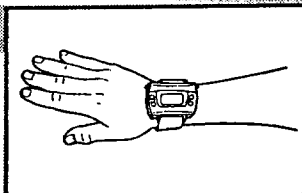
The right way

Wrist moves freely and comfortably
(Biographer should be at least 2 inches
from your wrist).



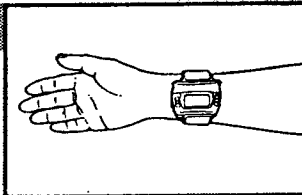
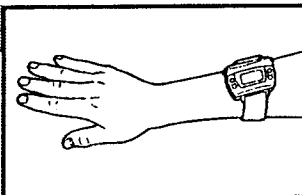
The wrong way

Wrist movement is restricted
(Biographer is too close to your wrist).



Recommended wearing sites

You may wear the
Biographer on either
side of your arm.



Cleaning the wearing site

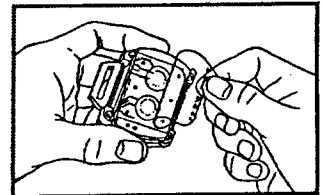
Once you have chosen a wearing site, take a minute to clean the skin at the site:

- Use an alcohol wipe to remove any dust or dirt from the skin surface
- Allow a few seconds for the skin to dry; then remove protective liner 2 from the AutoSensor as described below

Removing protective liner 2

Do not remove protective liner 2 until you are ready to put on the GlucoWatch® Biographer. To remove protective liner 2, pull the blue tab and peel off the protective liner:

- This uncovers the adhesive that makes the Biographer stick to your arm
- Discard the liner



Caution:

Remember, do not touch the sticky surface of the AutoSensor. Also, put on your GlucoWatch Biographer immediately, otherwise the gel collection discs on the AutoSensor may dry out.

Putting on the Biographer

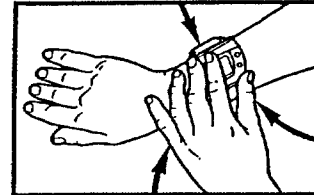
Holding the GlucoWatch Biographer by the sides:

- Step 1:** Carefully place the Biographer onto the selected wearing site.
- Step 2:** Press firmly on the Biographer. Pressing ensures that the adhesive on the AutoSensor makes a firm bond with your skin.
- Step 3:** Feed the strap through the D-ring.
- Step 4:** Pull the strap to tighten the band, making sure that the adhesive does not pull away from your skin.
- Step 5:** Join the 2 Velcro® pieces together to fasten.

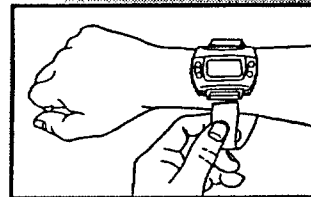


Tip: Fasten the watchband tightly

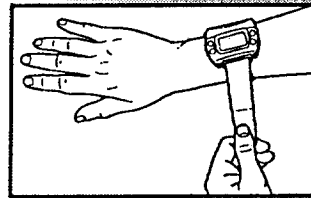
- Although the adhesive on the AutoSensor keeps the GlucoWatch Biographer in place, the band should be tightly fastened for extra security.
- If the Biographer moves while you are wearing it, some glucose measurements may have to be skipped or monitoring may automatically shut off.
- Be sure to check the band tightness periodically. If the band feels too loose or too tight, adjust as needed.



Step 2



Step 3



Step 4

TIME TO MONITOR



TIME TO MONITOR

GLUCOWATCH[®]


AUTOMATIC GLUCOSE BIOGRAPHER


Starting monitoring

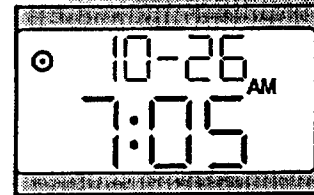
The GlucoWatch Biographer requires a nearly 3-hour warm-up period before you can calibrate it and begin the 12-hour monitoring period.

Step 1: Press and hold the  Start button until you hear 2 beeps. The  On indicator will now appear on the display.

Step 2: After the warm-up period, the alarm sounds to let you know that it's time to calibrate your GlucoWatch Biographer.

2a: Press the  Change button to shut off the alarm.

Note: If you have done a System Check and have gotten a FAIL result, the Biographer will not let you begin glucose monitoring. When you press the  Start button, the display will show FAIL again. Do the System Check again until you get a PASS result (see page 3.1) or call Technical Services for help.




Step 1



Starting monitoring (continued)

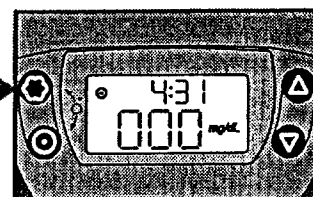
2b: You will see a flashing **CAL** message. Within the next 5 minutes, measure your blood glucose using a regular blood glucose meter and enter your finger-stick reading into the Biographer.




Step 2b



2c: Press and **hold** the  Change button until the **CAL** message is replaced by 3 zeros.

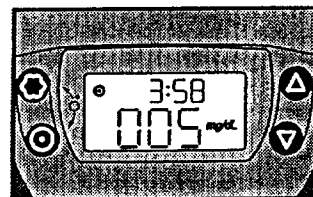
2d: Use the  or  button to replace the flashing zero with the number from your finger-stick test.



Step 2c

2e: Press the  Change button so the next zero flashes and repeat until all numbers are entered (from right to left).

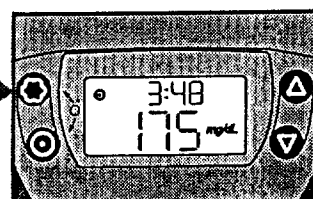
2f: Press the  Start button to confirm the calibration. Press the  Start button again to return to the time and date display.



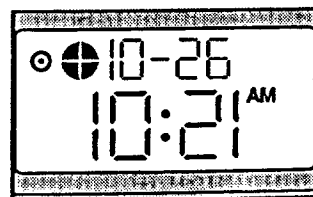
Step 2d

Step 3: Over the next 15 minutes, the GlucoWatch® Biographer completes an internal measurement matched to your finger-stick reading. When this internal measurement is completed, the Countdown timer will appear on the display.

Automatic glucose monitoring is now under way! The next 3 sections describe problems that can occur during this start-up process.



Step 2e



Step 3



Tip: For fast entry of your finger-stick readings

- Press and hold the **△** or **▽** button. The GlucoWatch Biographer will scroll through numbers at high speed and you can enter the digit you want
- When you follow this procedure, the Biographer automatically moves from the right digit to the left digit so you can enter the next number in a sequence

*Note: If you accidentally exit the CAL screen or input the wrong value, you can quickly return to it by pressing the **⊙** Start button to return to the time and date display. Then press the **▽** button once and you will see STAT on the upper display and CAL on the lower display. Press and hold the **⊙** Change button, then enter your calibration value.*

Problems that can occur during the warm-up period

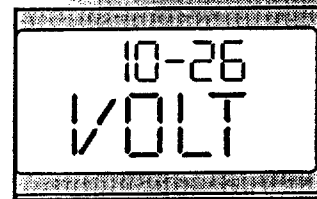
Under certain circumstances, the GlucoWatch Biographer may shut off during the first 5 minutes of the warm-up period. You will see one of the following on the display panel:

Flashing OFF message alternating with

VOLT: Indicates a problem with the electrical connection between the AutoSensor and the skin. This may be due to:

1) Too much hair at the site.

Solution: Pick a better wearing site. You may need to use a new AutoSensor if the adhesive is not sticky enough.



Problems that can occur during the warm-up period (continued)

2) Failure to remove protective liner 2 that exposes the adhesive on the AutoSensor.

Solution: Review the instructions on page 3.6 and try starting over with the same AutoSensor once you've removed the protective liner.

3) Removing the AutoSensor from its pouch too soon. This can cause the gel collection discs to dry out.

Solution: Start over with a new AutoSensor.

READ: Indicates that the AutoSensor isn't seated properly. This can result if the AutoSensor isn't correctly snapped into the back of the Biographer or if protective liner 1 was not removed.

Solution: Remove the AutoSensor, check to make sure protective liner 1 was removed, and try reinserting the AutoSensor. You may need to use a new AutoSensor if the adhesive is not sticky enough.



Problems that can occur during the calibration period

If you are unable to measure your blood glucose and enter your value within 5 minutes, just wait for the next calibration period. The alarm will sound, the display will appear as described in Step 2, and you will again have 5 minutes to enter your blood glucose value. This process will be repeated every 20 minutes until you successfully enter a calibration value.

The GlucoWatch® Biographer will not be able to use a calibration value outside of the range of 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L). If you try to enter a value outside of this range, the Biographer will display **SKIP** alternating with **DATA**. After 15 minutes, the alarm will sound to let you know it is time to calibrate your Biographer. Remember, your low or high blood glucose situation should be addressed immediately. Contact a health care professional for assistance if necessary.

Problems that can occur while the Biographer completes the first internal measurement

If a problem occurs during this critical period, you will need to do another finger-stick reading and enter a new calibration value.

- The Biographer will immediately go to the **CAL** screen and the alarm will sound. Press the **⊕** Change button to shut off the alarm
- Follow the instructions for calibration (Step 2) on page 4.1

You can continue trying to calibrate the Biographer every 20 minutes for up to 6 calibration attempts. Remember to do a new finger-stick reading each time you try to calibrate. Or, you can stop monitoring (see page 4.8) and try to start again with a new AutoSensor at a new site on your arm.


Calibration may be unsuccessful if the Biographer is not getting a strong enough signal, if you are perspiring, if the temperature is changing too rapidly, or if you enter a calibration value outside the range of 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L).



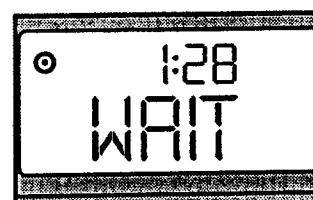
Tip: To prevent problems during the critical 15-minute period while the Biographer completes the first internal measurement, try to avoid:

- Excessive arm movement
- Extreme temperature changes

Checking on the status of the Biographer

At any time you can press the  button to check the status of the Biographer. The word **STAT** will appear briefly in the upper display, and the lower display will show one of the following codes:

| Code: | This means: |
|-------------|---|
| OFF | The warm-up process has not been started. See page 4.1 for instructions on how to start monitoring. |
| WAIT | The Biographer is warming up. The upper display will show the amount of time remaining in the warm-up period. The time will appear in hours and minutes until the last hour, then in minutes and seconds. |
| CAL | You can enter a calibration value into the Biographer now. The upper display will show the time remaining in the CAL period. |
| NEXT | The Biographer has been calibrated and glucose monitoring is under way. The upper display will show the time remaining until the next reading. |



Viewing your glucose readings

Checking your most recent reading

From the time and date display, press the **▲** button. You will see the most recent glucose measurement on the lower display. The upper display will alternate between the time and date of the measurement. If the glucose measurement triggered an alert, the measurement will alternate with the alert code: **HIGH**, **LOW**, or **DOWN**.

A trend arrow will appear if the glucose measurement is 18 mg/dL (1.0 mmol/L) above or below the previous reading.

Checking earlier readings

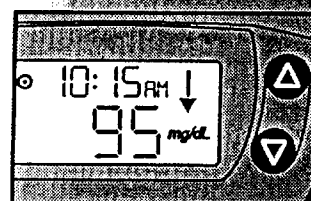
The GlucoWatch® Biographer stores 4,000 data points, including test results, event markers, and error messages. At any time, you can review as many readings as you like to determine your individual pattern of glucose changes and to chart your progress in controlling diabetes.

To see earlier readings, scroll backward by pressing the **▲** button. Press and **hold** the **▲** button to move quickly through the memory. When you reach the end of the stored data, you'll see a screen labeled **END**.

To return to the time and date screen, press the **⊙** Start button or wait 30 seconds until the time and date appear automatically.

Example:

If your glucose reading is 95 mg/dL (5.3 mmol/L) and is at least 18 mg/dL (1.0 mmol/L) below the previous reading, you will see:



Stopping monitoring

To stop glucose monitoring press both the Ⓢ Start button and the ⓐ Change button at the same time.

When you stop glucose monitoring, you will no longer see the Ⓢ On indicator or the ⓐ Countdown timer in the upper left corner of the display panel.

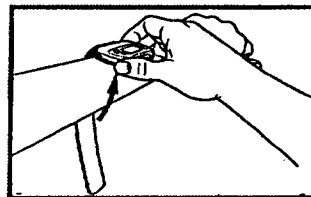
The word **OFF** will appear in the lower display alternating with the word **STOP**. The alarm will also sound. Press the ⓐ Change button to stop the alarm and then press the Ⓢ Start button to return to the time and date display.

Note: If the GlucoWatch® Biographer is worn beyond 12 hours after calibration, it will automatically stop glucose monitoring. You will see a flashing OFF alternating with END. Press the Ⓢ Start button to return to the time and date. The clock and memory functions will continue to operate.

When you stop glucose monitoring, you MUST replace the used AutoSensor before you can monitor again!

Removing the Biographer

The adhesive that makes the AutoSensor stick to your arm is quite strong. Remove the Biographer by first lifting up one corner and then “peeling” the Biographer off your arm.



Ensuring the accuracy of your Biographer Reading

In order to get the most accurate readings from your GlucoWatch Biographer, follow these recommendations:

- Run a System Check:
 - Before using the GlucoWatch Biographer for the first time
 - Every time you open a new box of AutoSensors
 - If the Biographer is dropped or potentially damaged in any way
- Before use, AutoSensors should generally be stored in a refrigerator (2°C to 8°C [36°F to 46°F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25°C or 77°F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month
- If you suspect that the AutoSensors may have been exposed to extreme temperatures, conduct a Quality Control (QC) Test before using them (see page 7.1)
- Always use the AutoSensor Press before attaching an AutoSensor to the Biographer
- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your regular blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test
- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier
- If you question a series of GlucoWatch Biographer readings during a 12-hour period, do not use another AutoSensor from the same box without running both a System Check on the Biographer and a QC Test on one of the remaining AutoSensors

THE GLUCOWATCH® BIOGRAPHER AND YOUR TREATMENT PLAN



Working your Biographer into your diabetes management plan

You want to stay out of trouble—today and in the future. That's what frequent blood glucose monitoring is all about. While you're busy living your life, your GlucoWatch Biographer is like a good friend—always there to remind you to take care of yourself.

Because you have your own lifestyle, it's important for you to consult with your health care team about how your GlucoWatch Biographer should fit into your routine. Together, you can figure out the best way to make your GlucoWatch Biographer a part of your treatment plan.

You may find that the best way to use your GlucoWatch Biographer is to wear it every day. Or, consider wearing your Biographer when you know you have a busy day ahead. You won't have to leave a meeting or interrupt your work to test your glucose.

Your GlucoWatch Biographer makes a great traveling companion, too. When you're on a long trip, all you have to do is check your Biographer to see if your blood sugar is under control.

Your GlucoWatch Biographer can even work while you're sleeping. You'll have the security of knowing that it can inform you of dangerous changes in your glucose levels.

Note: Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

Working your Biographer into your diabetes management plan (continued)

Your Biographer can help you understand the pattern of glucose changes that you experience each day. With 2 AutoSensors—one for each 12-hour wearing period—you can get a full 24 hours of readings. You should discuss with your health care team whether using the Biographer in this way prior to your visit would provide valuable information to help in managing your diabetes.

Your GlucoWatch Biographer also makes it easy to see the impact of activities on your blood sugar levels. The “Event” marker (see page 5.4) allows you to enter activities such as meals, insulin injections, sleep, and exercise. Reviewing these events together with your glucose readings can help you spot trends and gain knowledge about your condition. This can lead to improvements in your treatment program.

Note: When it is time to make an important decision, the Biographer should not be used as a “substitute” for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

Your GlucoWatch Biographer makes it simpler, more convenient, and less painful to stay on top of your diabetes in many ways. It gives you a better understanding of your blood sugar levels to help you gain better control of your diabetes.

Warnings:

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The Gluco Watch Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular glucose meter to check the Biographer results.
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a "sliding scale." If you use a sliding scale, be sure to confirm the Biographer reading with your regular blood glucose meter to make sure you take the right amount of insulin.
- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.
- Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a "substitute" for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

Setting an event marker





The "Event" marker allows you to keep a running record of certain events each day. By using this option, you can see how your day-to-day activities are affecting your glucose levels.

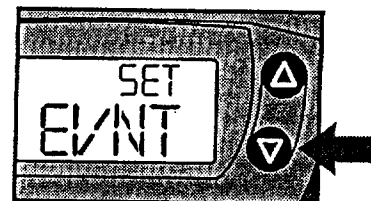
Event options

MEAL = Breakfast, lunch, or dinner
 SNAO = Between-meal snack
 INJ = Insulin injection
 SLEP = Went to bed
 WAKE = Woke up
 EXER = Exercise
 ILL = Illness

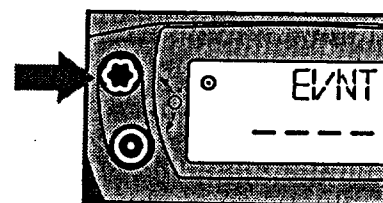
Note: An event marker is stored just like a glucose reading and can be viewed whenever you are checking your glucose trends.

To set an event marker:

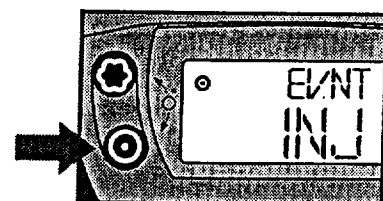
- Step 1:** From the time and date display, press the  button twice. You should see **SET EVNT**.
- Step 2:** Press and **hold** down the  button until you see **EVNT** and ---- flashing.
- Step 3:** Press the  button until the display screen shows the event you want.
- Step 4:** Press the  button to record the event.
- Step 5:** Your GlucoWatch® Biographer will return to the time and date display automatically.



Step 1



Step 2



Step 4


USING THE GLUCOWATCH® BIOGRAPHER ALERT SYSTEM

**USING THE GLUCOWATCH®
BIOGRAPHER ALERT SYSTEM**

GLUCOWATCH[®]








AUTOMATIC GLUCOSE BIOGRAPHER

The High Glucose Alert

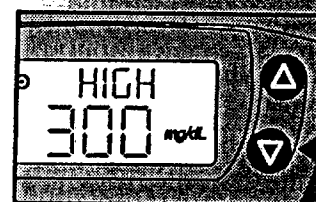
To help you reduce high blood glucose, your GlucoWatch Biographer has a built-in High Glucose Alert. The alert sounds when your glucose level rises above a preset limit. The alert beeps more and more frequently until you press the  Change button. The Biographer displays the glucose reading alternating with the word **HIGH**.

Changing the High Glucose Alert level

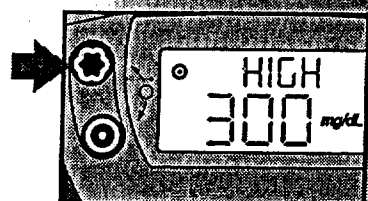
When you receive your new GlucoWatch Biographer, the High Glucose Alert level is preset at 300 mg/dL (16.7 mmol/L). Based on your individual needs, you and your health care team may decide to change the setting for the High Glucose Alert. Here's how to do it:

- Step 1:** From the time and date display, press the  button 3 times until you see the word **HIGH** in the upper display.
- Step 2:** Hold down the  Change button until the far right digit begins flashing.
- Step 3:** Use the  and  buttons to set the correct number. Press the  Change button to move to the next digit.
- Step 4:** Repeat Step 3 until all digits are set correctly.
- Step 5:** Check to make sure numbers are correct; then press the  Start button to store the value.
- Step 6:** Press the  Start button to return to the time and date display.

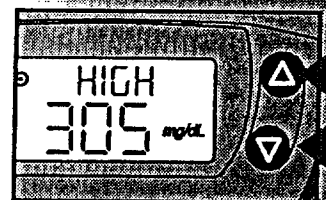
Example:
To change your
High Glucose Alert
to 195 mg/dL
(10.7 mmol/L):



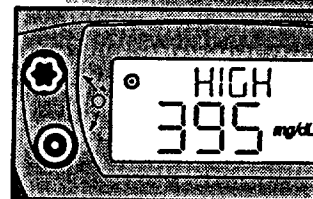
Step 1



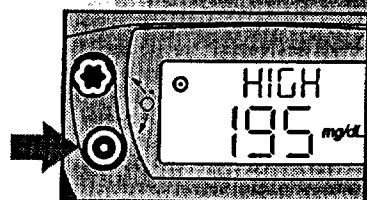
Step 2



Step 3




Step 4



Step 5








6-1

The Low Glucose Alert

Your GlucoWatch® Biographer can also help you reduce the risk of low blood glucose with a built-in Low Glucose Alert. The Biographer sounds an alert to let you know that your glucose level has passed the preset limit set by you and your health care team. The alert beeps more and more frequently until you press the  Change button. The Biographer displays the glucose reading alternating with the word **LOW**.

Changing the Low Glucose Alert level

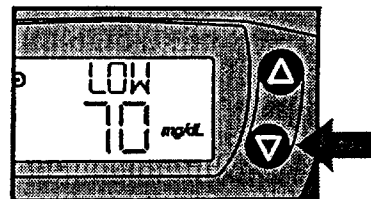
When you receive your new GlucoWatch Biographer, the Low Glucose Alert is preset at 70 mg/dL (3.9 mmol/L). Based on your individual needs, you and your health care team may decide to change the setting. Just follow these steps:

- Step 1:** From the time and date display, press the  button 4 times until you see the display that says **LOW**.
- Step 2:** Hold down the  Change button until the digit on the right begins flashing.
- Step 3:** Use the  and  buttons to set the correct digit. Press the  Change button to move to the next digit.
- Step 4:** Repeat until all digits are set correctly.
- Step 5:** Check to make sure numbers are correct, then press the  Start button to store the values.
- Step 6:** Press the  Start button again to return to the time and date display.

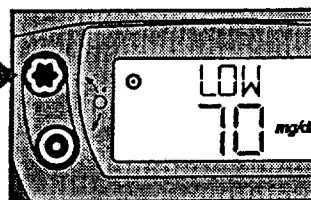
Caution:

Be sure to set the Low Glucose Alert level 20 to 30 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert at 80 or 90 mg/dL. Otherwise, the GlucoWatch Biographer may miss some low blood glucose events and the alarm will not sound.

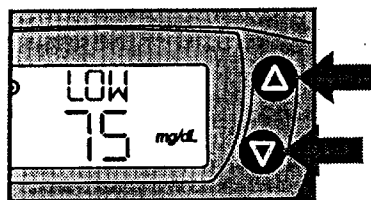
Example:
To change your
Low Glucose Alert
to 85 mg/dL
(4.7 mmol/L):



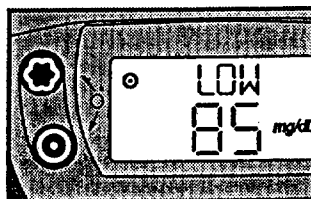
Step 1



Step 2




Step 3



Step 4

The Rate of Decline Alert

The GlucoWatch Biographer will automatically alert you if any glucose reading is 35% or more below the last reading. The alarm beeps more and more frequently until you press the  Change button. The Biographer displays the glucose reading alternating with the word **DOWN**.

You cannot change the Rate of Decline Alert feature of your GlucoWatch Biographer in any way.

Note: Your GlucoWatch Biographer can read glucose levels between 40 mg/dL and 400 mg/dL (2.2 mmol/L and 22.2 mmol/L). If your glucose levels are outside of this range, a reading will appear on the Biographer display as <40 mg/dL (<2.2 mmol/L) or >400 mg/dL (>22.2 mmol/L). You can set your individual alert levels anywhere in between these values.

Caution:

Remember that Biographer readings can sometimes be different from finger-stick test results. You must not rely on the Biographer to alert you every time your glucose is too high or too low. Never ignore symptoms that may be due to low blood glucose or high blood glucose.

SPECIAL FUNCTIONS

SPECIAL FUNCTIONS



Conducting a Quality Control (QC) Test on your AutoSensors

The Quality Control (QC) Test helps you ensure that your glucose readings are as accurate as possible.

- Conduct a QC Test if you suspect that the AutoSensors have been exposed to extreme temperatures
- If you question a series of GlucoWatch Biographer readings during a 12-hour period, do not use another AutoSensor from the same box without running both a System Check on the Biographer and a QC Test on one of the remaining AutoSensors
- If you are unable to successfully calibrate the Biographer, you may want to check one of the remaining AutoSensors by running a QC Test

It will take 50 minutes to complete the QC Test. Before you conduct the QC Test, make sure that you have the following items:

- Your GlucoWatch Biographer with a fully charged Ni-MH battery
- The AutoSensor Press
- A new AutoSensor
- A new tube of QC Test Solution
- A new QC Test Well with adhesive label








Tip: To obtain QC Test materials

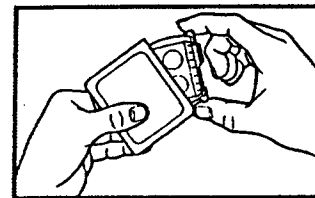
- QC Test Solution and Wells are available in a separate kit. If you're having trouble obtaining a QC Test Kit, call Technical Services for assistance at 1-866-GLWATCH

Conducting a QC Test (continued)

To conduct the test, follow these steps:

- Step 1:** Remove the AutoSensor from its pouch. Go to page 3.2 and follow the procedure for using the AutoSensor Press.
- Step 2:** Connect the AutoSensor to the GlucoWatch® Biographer, but **leave protective liner 2 in place**. (See pages 3.3 and 3.6).
- Step 3:** From the time and date display, press the  button 7 times. The display will read **QC MODE**.
- Step 4:** Press and **hold** the  Change button until **QC** appears on the upper display and **OFF** flashes on the lower display.
- Step 5:** Use the  or  button until **ON** flashes on the lower display.
- Step 6:** Press the  Start button to begin the test. **WAIT** will appear in the lower display and the time remaining (20:00, or 20 minutes) will appear in the upper display.

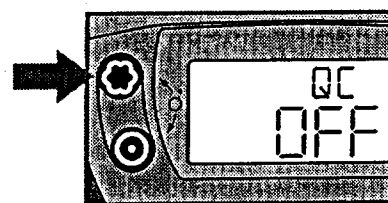
Note: You can set the Biographer down on either side during the 20-minute WAIT Period.



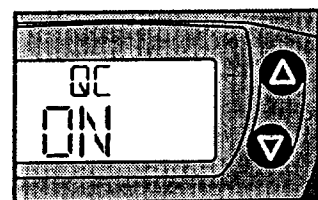
Step 1



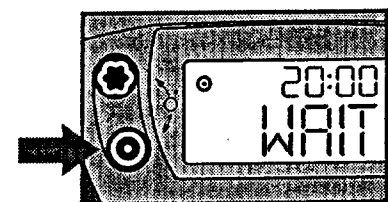
Step 3



Step 4



Step 5



Step 6

Conducting a QC Test (continued)

Step 7: After 20 minutes, the alarm will sound. The lower display will now read **GLUC** (glucose) and the upper display will show the time reset to 5 minutes. Press the **Change** button to confirm that you have heard the alarm.

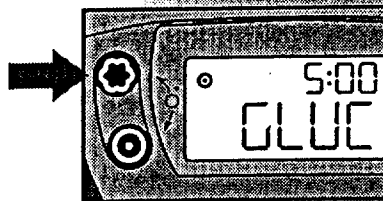
During this 5-minute period, you need to complete steps 8 through 12:

Step 8: Remove protective liner 2 from the AutoSensor by pulling the blue tab and peeling off the liner.

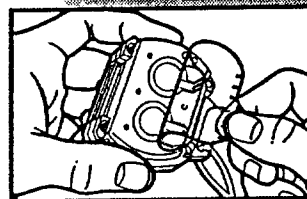
Step 9: Place the QC Test Well on the AutoSensor, making sure that the inside of the Well faces down and that the flat portion of the Well covers the entire surface of the 2 gel collection discs. Press firmly around the edges of the QC Test Well to ensure good contact with the AutoSensor.

Step 10: Snap the top off of the tube of QC Test Solution.

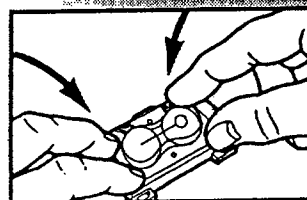
Step 11: Squeeze the solution into the hole in the QC Test Well. Make sure the QC Test Well is full. It may help to tilt the Biographer while filling the Well to prevent air bubbles.



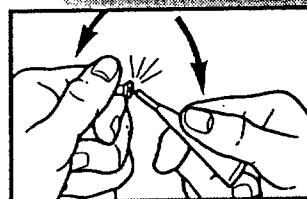
Step 7



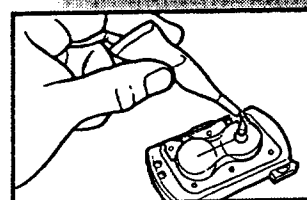
Step 8



Step 9



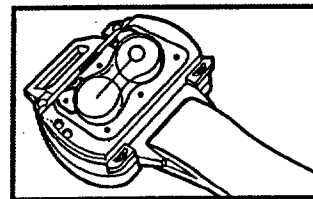
Step 10



Step 11

Conducting a QC Test (continued)

Step 12: Place the adhesive label over the hole in the QC Test Well to prevent leaking. Leave the Biographer face down for the rest of the QC Test.





Step 12

After the 5-minute period ends, a new 25-minute countdown period begins:


Step 13: After 25 minutes, the alarm will sound. (The alarm will sound earlier if an error occurs during the test.) Turn the Biographer over and press the **Change** button to confirm that you have heard the alarm.

Note: The QC Test Solution is a glucose solution that will not harm the skin or clothing.

Step 14: Compare the readout on the display to the value printed on the QC Test box to determine the results of the test.

| If the display reads: | This means: | Your next step: |
|--|---|--|
| <p>QC on the upper display with a numeric value on lower display</p>  | <p>The test has been completed.</p> | <p>Compare the value shown on the lower display with the value printed on the QC Test box.</p> <ul style="list-style-type: none"> • If the displayed value is equal to or greater than the value on the box, you can begin glucose monitoring by removing the used AutoSensor and QC Test Well and inserting a new AutoSensor from the same box • If the displayed value from the QC Test is below the value printed on the QC Test box, the box of AutoSensors should not be used for glucose monitoring |
| <p>QC on the upper display and ERR on the lower display</p>  | <p>An error was encountered during the QC Test (for example, a change in temperature or dropping the Biographer).</p> | <p>Start the test over again with a new AutoSensor, tube of QC Test Solution, and QC Test Well.</p> |

Conducting a QC Test (continued)

Step 15: Press the  Start button to return to the time and date display.

Caution:

If your QC Test value is below the value printed on the box, the box of AutoSensors should not be used. If this happens you should:

- *Call Technical Services for assistance with returning the failed box of AutoSensors.*

Step 16: Remove and discard the AutoSensor and QC Test Well.

Note: The AutoSensor, tube of QC Test Solution, and QC Test Well used for the QC Test cannot be reused. If you did not place the QC Test Well and QC Test Solution onto the AutoSensor before the end of the 5-minute application period, you will need to use a new AutoSensor and restart the test.

Changing the Biographer settings

You can change the default settings for your GlucoWatch® Biographer to be just right for you. The settings that can be changed are shown in the following table.

| Item | Choices | Default Setting |
|--------------|---------------------------|-----------------|
| Language | See below | English |
| Glucose unit | mg/dL or mmol/L | mg/dL |
| Clock | 12-hr or 24-hr | 12-hr |
| Date | day/month or month/day | month/day |
| Beep | ON or OFF | ON |
| Alert option | MOST or ALL | MOST |

Understanding the beep

The GlucoWatch Biographer has been preset to **ON** to sound a beep whenever a button is pressed. Changing this setting to **OFF** eliminates these beeps.

Understanding the alert option

Your GlucoWatch Biographer will always alert you to the following circumstances:

- *If your glucose falls above or below the alert levels you select with your health care team.*
- *Rapidly declining glucose levels.*
- *A skipped reading due to perspiration.*
- *Any type of shut-off.*


When the GlucoWatch Biographer alert option is set to **MOST**, you will hear a beep in these circumstances only.

However, the GlucoWatch Biographer has another alert option: **ALL**. When the Biographer is set to **ALL**, you will hear a beep for all of the circumstances listed above, as well as:

- Each time a new glucose reading is available (every 20 minutes)
- At the end of each 12-hour monitoring period
- When a reading is skipped for reasons other than perspiration


Your GlucoWatch Biographer is preset to **MOST**.

The GlucoWatch Biographer “beeps” and what they mean


| Description of sound | What the sound means |
|--|--|
| A beep that becomes more and more frequent (until you press the  Change button) | <p>Indicates a potentially serious condition:</p> <ul style="list-style-type: none">• Low glucose• High glucose• Rapid decline in glucose (35% or more since last reading)• Excessive perspiration (may signal low glucose)• An unexpected shut off of glucose monitoring <p>If you've selected ALL, it could also indicate the following conditions:</p> <ul style="list-style-type: none">• A skipped glucose reading• The end of the 12-hour monitoring period |
| 2 beeps | If you've selected ALL, this sound indicates that a new glucose reading is available |

Changing the settings

(A) Entering the SET MODE

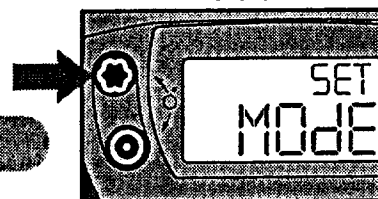
Step 1: Start at the time and date display. Press the  button 6 times.

Step 2: You should now see **SET** and **MODE**.

Step 3: Hold the  Change button until you see **LANG** on the upper display and **ENGL** on the lower display.





Step (A) 1




Step (A) 2

(B) Selecting a language

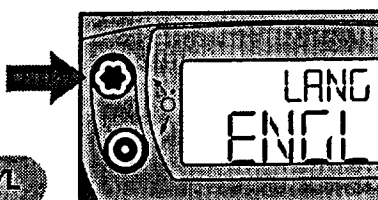
Step 1: The **LANG** screen will appear and **ENGL** will start flashing. Press the  or  button to move through choices until the language you want appears:

| | |
|-------------------|-----------------|
| ENGL = English | FRAN = French |
| SVEN = Swedish | DAN = Danish |
| PORT = Portuguese | SUOM = Finnish |
| NL = Dutch | NOR = Norwegian |
| ESPN = Spanish | PLSK = Polish |
| ITAL = Italian | CES = Czech |
| DEUT = German | |

Step 2: Press the  Change button to move to the next subject.



Step (B) 1




Step (B) 2

(C) Selecting units of measurement for glucose: mg/dL or mmol/L

Step 1: You should see the **GLUC** screen with a flashing --- mg/dL or --- mmol/L.

Step 2: Press the  or  button to select **mg/dL** or **mmol/L**.

Step 3: Press the  Change button to move to the next subject.



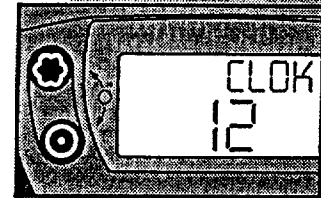
Step (C) 1

(D) Selecting a 12-hour (AM/PM) or 24-hour clock format

Step 1: You should see the **CLOCK** screen with a flashing **12** or **24**.

Step 2: Press the **▲** or **▼** button to select the clock you want.

Step 3: Press the **⊙** Change button to move to the next subject.

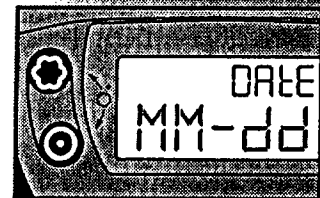


Step (D) 1

(E) Selecting day/month or month/day format

Step 1: You should see the **DATE** screen with a flashing **dd-MM** (day/month) or **MM-dd** (month/day).

Step 2: Press the **▲** or **▼** button to select the option you want.

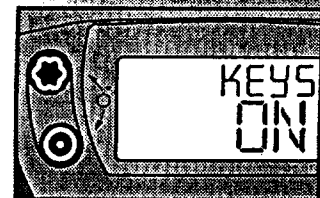


Step (E) 1

(F) Selecting the beep

Step 1: You should see the **KEYS** screen with a flashing **ON** or **OFF**.

Step 2: Press the **▲** or **▼** button to select the option you want.

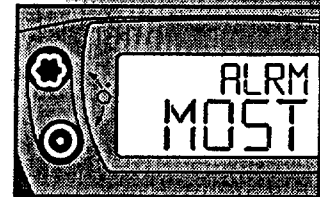


Step (F) 1

(G) Selecting the alert option

Step 1: You should see the **ALRM** screen with a flashing **MOST** or **ALL**.

Step 2: Press the **▲** or **▼** button to select the option you want.



Step (G) 1

(H) Saving the settings

Step 1: Press the **⊙** Start button to confirm all of your choices.

Step 2: Press the **⊙** Start button again to return to the time and date screen.

ALL ABOUT POWER

ALL ABOUT POWER



Power levels and battery life

Your GlucoWatch Biographer runs on 1 rechargeable nickel metal hydride (Ni-MH) AAA battery. It also contains 1 internal backup lithium battery. A built-in power-saving mode conserves battery life.

Rechargeable Ni-MH battery: With each new monitoring period, you must use a fresh (new or recharged) Ni-MH battery (see page 2.2 for recharging instructions).

If necessary, you can substitute an alkaline AAA battery for a Ni-MH battery.

Note: Never put an alkaline battery in the charger you get with your GlucoWatch Biographer.

Caution:

Do not use any other type of rechargeable battery in your GlucoWatch Biographer.

Backup lithium battery: Saves the date, time, and glucose readings in memory while the Ni-MH battery is being changed. By itself, the lithium battery can only maintain the memory for about 2 days. The main power source (the Ni-MH battery) constantly recharges the backup lithium battery.

If the backup lithium and Ni-MH battery are both depleted, you will lose memory storage of your glucose readings as well as the date and time. If this happens, you must reset the Biographer (see page 8.4).



Tip: To preserve data stored in your GlucoWatch Biographer

- Replace the Ni-MH battery every month, even if the Biographer is not being used

GlucoWatch® Biographer: the various levels of power

When the Ni-MH battery is getting low, the alarm will sound and you will see a **BAT** message in the upper display. This means that the GlucoWatch Biographer can no longer make glucose readings but there's enough energy to operate other functions. You must change the Ni-MH battery before you start monitoring.

Your GlucoWatch Biographer also has a power-save mode. The display will be off, but the Biographer will save previous glucose values as well as the date and time of the readings. You can put the GlucoWatch Biographer into the power-save mode manually, or it will go into the power-save mode automatically approximately 6 hours after the **BAT** message appears.




If the GlucoWatch Biographer stays in the power-save mode for more than about a month (with a fully charged Ni-MH battery in place), both the lithium and Ni-MH batteries will completely discharge, all operations will stop (including the clock), and stored readings will be lost. You will then have to reset the Biographer to restore normal functions (follow the instructions on page 8.4).

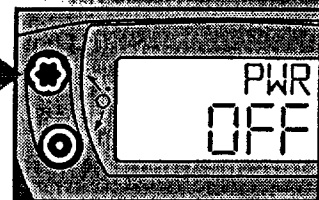
Power-save mode

The GlucoWatch Biographer conserves energy with a power-save mode. You can shut off the display and function buttons before long periods when the Biographer won't be used. This will keep the internal memory going for as long as possible.

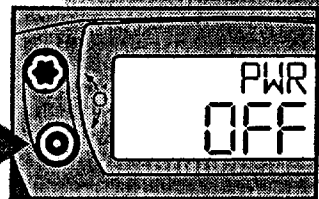
It's best to start with a fully charged Ni-MH battery. This will help keep your lithium battery charged when you want to keep your Biographer in the power-save mode for an extended period of time. Be sure to put the System Check Sensor onto the Biographer so that the battery stays in place.

Activating the power-save mode

- Step 1:** From the time and date display, press the  button 8 times. The screen should display **PWR** and **OFF**.
- Step 2:** Hold down the  Change button until the word **OFF** starts flashing.
- Step 3:** Press the  Start button and the Biographer will turn off. You are now in the power-save mode.



Step 2



Step 3

Turning the Biographer on

- Step 1:** Put in a recharged Ni-MH battery and wait approximately 10 seconds.
- Step 2:** Your GlucoWatch Biographer will respond in 1 of 2 ways:
- The Biographer will "wake up" and the correct time and date display will reappear
What to do next: Insert a new AutoSensor and follow the normal monitoring procedures
 - The Biographer will "wake up" with all elements on the display illuminated, or the display will remain blank
What to do next: Follow the steps for resetting your Biographer on page 8.4

Resetting your Biographer

If both power sources (the main Ni-MH and lithium batteries) have run down or if you need to clear your stored data, you must reset your GlucoWatch® Biographer.

To reset, follow these steps:

Step 1: Remove the sensor on the back of the Biographer—either the System Check Sensor or the AutoSensor.

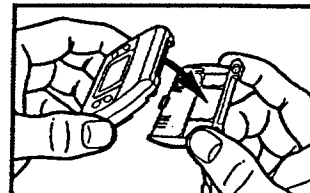
Step 2: Insert a fully charged Ni-MH battery.

Step 3: Press the tip of a pencil or a narrow object into the reset button on the back of the Biographer.

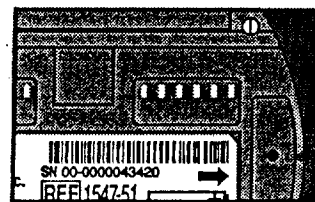
Step 4: Put the sensor back on the Biographer—either the System Check Sensor or the AutoSensor. After it is reset, the Biographer will take a few seconds to return to the original time and date screen.

Step 5: See page 2.14 to reset the correct time and date.

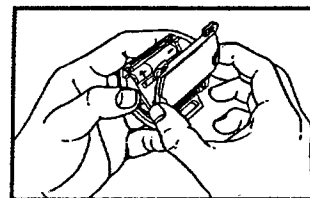
Note: Once the Reset button has been pushed, the Biographer will erase all customized settings and stored data.



Step 1



Step 3



Step 4

TROUBLESHOOTING



How the Biographer identifies potential problems

Throughout the warm-up and 12-hour monitoring periods, your GlucoWatch Biographer constantly checks to make sure the system is operating properly.

When the Biographer is reading your glucose levels, 2 types of problems may arise:

Problem 1: The Biographer skips an individual glucose reading, but continues with the next scheduled reading.

Problem 2: The Biographer stops monitoring. The Biographer alert will sound. To begin monitoring again, you must replace the AutoSensor and start over. (You must redo the warm-up and calibration steps.)

Note: When your GlucoWatch Biographer stops monitoring, you will always hear an alert. When the Biographer skips a measurement, you will hear an alert only if the reading was skipped due to perspiration (unless you have selected ALL for the additional alert options, see page 7.7).

When the Biographer skips a reading

Some conditions (such as too much perspiration or rapid temperature changes) may cause the GlucoWatch® Biographer to skip a reading. If this happens, you will see a **SKIP** message alternating with an identifying code. Try to correct the condition as soon as possible. The Biographer will attempt to take another reading in 20 minutes.

Codes for a skipped reading

TEMP: Any dramatic change in skin temperature can prevent a reliable reading. Did you start out in a warm building, then go outside on a cold day? Did you just get into a car that's been in the sun?

COLD: Your skin temperature is too cold. Try covering the Biographer with your sleeve, a sweater, or a jacket.

DATA: Inconsistencies in results suggest that the current glucose value may not be reliable. This can occur if the Biographer is bumped or if you are moving your arm excessively.




Tip: If you have 2 or more **SKIP DATA** messages in a row, you may want to recalibrate the Biographer. See page 9.6 for details.

Codes for a skipped reading (continued)

PRSP: A reading can't be completed because the perspiration detector discovered an excessive amount of sweat. The alert will sound because perspiration can be caused by low blood glucose. If the Biographer skips too many readings due to perspiration during the 12-hour monitoring period, it will stop monitoring.

If you get a SKIP message and the alarm sounds due to perspiration

- Press the  Change button to confirm that you have heard the alert
- Consider the possibility that your perspiration may be due to low blood glucose. Test your blood glucose with your regular blood glucose meter or contact a health care professional if necessary

Note: Your GlucoWatch Biographer will shut off automatically if 6 SKIP messages are recorded in a row.

When glucose measurement stops

If a problem occurs that is serious enough to shut down the glucose monitoring function, an alarm will sound and the display will flash **OFF** alternating with an identifying code. To begin monitoring again, remove and discard the AutoSensor. Connect a new AutoSensor and start over. (See directions on page 3.3.) If the problem occurs frequently or you can't get the GlucoWatch® Biographer to start up again, call our Technical Services Department toll free at 1-866-GLWATCH.

Codes for problems that stop glucose measurements

OFF will flash alternating with one of the following codes:

| Code: | This means: | Your next step: |
|--------------|--|---|
| VOLT | <p>The Biographer has reached the high voltage limit for safe use. This means there's a bad electrical connection between the AutoSensor and your skin. This can happen if:</p> <ul style="list-style-type: none"> • There's too much hair • The adhesive bond is broken between the Biographer and the skin • The gel collection discs have dried out | <p>Try to determine what happened before you start monitoring again with a new AutoSensor.</p> |
| PRSP | <p>The perspiration detector found too much sweat on too many readings in a row. Too much perspiration makes continued glucose readings unreliable. Remember that perspiration can be caused by low blood glucose.</p> | <p>Remove the GlucoWatch Biographer and allow the back of the Biographer to dry. After you have cooled down and are no longer perspiring, you may begin monitoring again with a new AutoSensor.</p> |
| READ | <p>The GlucoWatch Biographer can't measure the signal produced by the reaction of glucose in the gel collection discs. Several things could cause this to happen:</p> <ul style="list-style-type: none"> • The AutoSensor may not be properly seated on the back of the Biographer • There's a poor connection between the AutoSensor and the contacts on the back of the Biographer • There could be a small amount of water between the AutoSensor and the contacts • A series of data inconsistencies may have occurred such that further readings cannot be reliably completed • Six readings in a row may have been skipped • Protective liner 1 has not been removed | <p>Try to determine what happened before you start monitoring again with a new AutoSensor. Make sure that you have snapped the AutoSensor correctly onto the Biographer.</p> |

Recalibrating the Biographer

You may want to recalibrate the GlucoWatch® Biographer if you discover that you made a mistake when entering your calibration finger-stick value, if your readings are inconsistent with your physical symptoms, or if you get 2 or more **SKIP DATA** messages in a row.

A new calibration value can be entered into the GlucoWatch Biographer during any 5-minute calibration period. Follow these steps:

Step 1: Press the **⏏** button 5 times until you see a display that reads **SET CAL**.

Step 2: After a couple of seconds the display will change to either

- **WAIT** on the lower display with 15 minutes or less remaining on the upper display
- OR
- **CAL** alternating with — — — — **mg/dL** or **mmol/L** on the lower display with 5 minutes or less remaining on the upper display

Step 3: If the display reads **WAIT**, simply wait to do your finger-stick reading until the time remaining reaches 0:00 and the calibration period begins. The display will change to **CAL** alternating with — — — — **mg/dL** or **mmol/L** on the lower display with 5 minutes remaining on the upper display.

*Note: The Biographer will not automatically return to the time and date from the WAIT display. You must press the **⏏** Start button to return to the time and date display. Also, the alert will not sound when the calibration period begins. You will need to keep an eye on the time remaining so you will know when to do the calibration.*

Step 4: Test your blood glucose level using a finger-stick and any regular blood glucose monitoring system. Enter the value into the GlucoWatch Biographer. **Follow the instructions on page 4.2 beginning with Step 2b.**

Step 5: Remember to press the **Ⓢ** Start button **twice** to confirm the calibration value and return to the time and date display.

Step 6: Fifteen minutes after you enter the calibration value, the GlucoWatch Biographer completes an internal measurement matched to your finger-stick reading. The Countdown timer will not appear on the display. The Countdown timer will appear again after the Biographer measurement is completed and matched to your finger-stick reading.

Note: If a problem occurs during this critical period, the Biographer's alert will sound and you will need to repeat the recalibration procedure.

Codes for problems with the Biographer's memory

Three types of memory errors may occur with your GlucoWatch® Biographer. The following table identifies these errors and explains what you should do next should such an error occur.

| Identifying codes: | This means: | Your next step: |
|--|--|--|
| Upper display reads ERR and lower display reads M1 | An error has occurred with the Biographer's memory causing stored glucose readings to be lost. | Press the ⊙ Start button to return to the Time and Date display to resume glucose monitoring as normal. If this error occurs frequently, call Technical Services to arrange for repair or replacement of your Biographer. |
| Upper display reads ERR and lower display reads M2 OR Upper display shows the time and date and the lower display flashes ERR and M2 . | A potential error has occurred with the Biographer's settings or memory of your Low and High Glucose Alert levels. | Re-enter all of the Biographer settings (See page 7.8) and your Low and High Glucose Alert levels. Then insert a freshly charged Ni-MH battery. If the error message displays again, contact Technical Services immediately to arrange for repair or replacement of your Biographer. |
| Upper display reads ERR and lower display reads M3 OR Upper display shows the time and date and the lower display flashes ERR and M3 . | An error has occurred with the Biographer's operating system. | Replace the current battery with a freshly charged Ni-MH battery. If the error message displays again, contact Technical Services immediately to arrange for repair or replacement of your Biographer. |

ADDITIONAL INFORMATION

GLUCOWATCH[®]

AUTOMATIC GLUCOSE BIOGRAPHER

Caring for and storing your Biographer

Your GlucoWatch Biographer is simple to use and easy to maintain. Generally, all it takes to keep it in good working order are careful handling and regular cleaning. Just follow these easy guidelines for maintaining your Biographer:

Keep it clean

Especially where the AutoSensor connects. Use an alcohol wipe to clean the Biographer when needed.

Store it carefully

- If you expect that you won't use your Biographer for some time, insert a new or freshly charged Ni-MH battery and put the Biographer into the power-save mode (see page 8.2). Store your Biographer with the System Check Sensor in place
- Before use, AutoSensors should generally be stored in a refrigerator (2°C to 8°C [36°F to 46°F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25°C or 77°F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month

Handle it gently

Dropping or bumping the Biographer can damage the electronics. Rough handling can also disrupt the connection with the skin. If this happens, glucose monitoring may shut off.

Avoid prolonged exposure to extremes in temperature or humidity

Do not store the Biographer or the AutoSensors in your car.

Keep it dry

Never immerse your Biographer in water. Permanent damage is likely to result if water or other liquids get inside of the Biographer. Your Biographer is splash-resistant, not waterproof.

Caution:

Do not take the GlucoWatch® Biographer apart. You could damage sensitive parts and your results could be inaccurate. Taking the Biographer apart will also invalidate the warranty.

Skin care tips

After wearing your GlucoWatch Biographer, you may notice

- Two red and slightly bumpy circular patches on your skin where the gel collection discs were
- A slight red mark from the edges of the Biographer

You may also experience some itching. These symptoms should disappear within about a week. They can be minimized by

- Rotating wearing sites
- Keeping irritated skin clean and dry
- Avoiding scratching irritated areas
- Protecting irritated areas from the sun
- Using a lotion on irritated skin **after** removing the Biographer

Some people have sensitive skin and may experience severe redness or itching after wearing the Biographer. If you experience severe skin irritation, contact a member of your health care team for advice.

Caution:

If any irritation persists for over 1 week, consult your physician.

Questions and answers

Note: A blood glucose monitoring program should be conducted under the guidance of your diabetes management team. Always consult a member of your diabetes management team before making changes in your treatment program.

The following pages provide answers to frequently asked questions about home glucose monitoring and the GlucoWatch Biographer. If you have a question that's not covered here, consult a member of your diabetes management team or call our Technical Services Department at 1-866-GLWATCH.

Q ■ Why should I test my glucose (sugar) levels?

A ■ No doubt your diabetes management team has explained the importance of keeping your blood sugar level under control. Your GlucoWatch Biographer helps you determine your degree of control by monitoring your glucose level. The test results provide a good picture of how diet, exercise, and medication are affecting your diabetes.

Test results can also indicate whether your diabetes has changed in ways that might require an adjustment in your treatment plan.

Q ■ Should my test results always be the same?

A ■ No. Results may vary, depending on your diet, activity level, and the time of day. These variations provide useful clues about your condition and how well your treatment program is working.

With the help of your diabetes management team, you can determine your own personal target glucose values, as well as what an unusually high or low reading is for you. In most cases, your results should stay within the range you determine.

Q ■ What steps can I take to ensure that my readings are accurate?

- A** ■
- Run a System Check:
 - Before using the GlucoWatch® Biographer for the first time
 - Every time you open a new box of AutoSensors
 - If the watch is dropped or potentially damaged in any way
 - Before use, AutoSensors should generally be stored in a refrigerator (2°C to 8°C [36°F to 46°F]). Do not store AutoSensors in the freezer. If needed, AutoSensors can be stored at room temperature (below 25°C or 77°F) for up to 1 month. AutoSensors stored at room temperature must be used within 1 month
 - If you suspect that the AutoSensors may have been exposed to extreme temperatures, conduct a Quality Control (QC) Test before using them (see page 7.1)

- Always use the AutoSensor Press before attaching an AutoSensor to the GlucoWatch Biographer
- Do not use an expired AutoSensor. Check the expiration date on the package label before use
- Use the AutoSensor immediately after opening the pouch. Do not store AutoSensors in open pouches
- Check the gel collection discs in the AutoSensor for any spots or areas of different color. The gel collection discs should have a uniform but "cloudy" appearance and are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration
- The accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time
- If you question the finger-stick reading that you plan to use for calibration, repeat the finger-stick test
- If you question a Biographer reading, use your regular blood glucose meter to do a finger-stick test. Keep in mind that Biographer readings correspond to blood glucose values from about 15 minutes earlier
- If you question a series of GlucoWatch Biographer readings during a 12-hour period, do not use another AutoSensor from the same box
 - without running both a System Check
 - and
 - a QC Test on one of the remaining AutoSensors

Q ■ What if my glucose readings are consistently high for my own diabetes control plan?

A ■ Your goal is to keep the amount of glucose in your blood as close to normal as possible. Normal, low, and high glucose values for your treatment plan should be determined with your diabetes management team. If your glucose readings remain consistently high, contact your health care team.

Q ■ What are the target glucose values associated with well-controlled diabetes?

A ■ Your own target glucose values should be determined with your health care team. If your glucose readings are frequently too low or too high, consult your health care team.

Your regular blood glucose meter gives test results that are either:

- **whole blood** glucose values, or
- **plasma** glucose values

All meters use whole blood to begin the test. The difference comes with how the result is calculated. Check the instructions for your meter to find out what kind of values it gives.

The Biographer readings are based on the finger-stick test result you use to calibrate the Biographer. This means that if your meter gives whole blood glucose values, the Biographer readings will also be whole blood values. If your meter gives plasma glucose values, the Biographer readings will be plasma values.

Target glucose levels for people with diabetes depend on what type of result your meter and the Biographer provide. The table below shows the general targets suggested by the American Diabetes Association.²

| | If your regular meter provides whole blood glucose values: | If your regular meter provides plasma glucose values: |
|---------------|---|--|
| Before meals: | 80-120 mg/dL | 90-130 mg/dL |
| At bedtime: | 100-140 mg/dL | 110-150 mg/dL |

Q. With the GlucoWatch® Biographer, my glucose measurement is different than the reading I get at the same point in time with my regular blood glucose meter. Why is that?

A. Remember that it takes time for the GlucoWatch Biographer to collect and measure glucose. ***Each glucose reading from your GlucoWatch Biographer actually reflects what your finger-stick reading would have been approximately 15 minutes earlier.*** Blood glucose values can change rapidly, especially after you've eaten. So the **lag time** between the readings produced by the Biographer and your regular blood glucose meter is one explanation for the difference.

The source of the glucose can also affect your measurements. Glucose values differ depending on whether they are based on a blood sample taken from capillary blood (via a finger-stick), interstitial fluid*

***Interstitial fluid is the fluid between the cells in the skin.**

(via the GlucoWatch® Biographer), or venous blood (usually drawn from a vein in the arm during a lab test). So the values do not match precisely.

Finally, the accuracy of the Biographer depends on the accuracy of the blood glucose test used for calibration. Be sure to check your blood glucose meter and test strips according to the instructions. Your doctor may also want to check your meter against a standard lab test from time to time. Be sure to perform the calibration procedure carefully (see page 4.1).

The GlucoWatch Biographer pulls glucose contained in interstitial fluid through the skin so it can be measured.

Testing principle

How the GlucoWatch Biographer measures glucose levels

The GlucoWatch Biographer works through a process called reverse iontophoresis. This process allows the Biographer to collect glucose samples through intact skin by application of an extremely low electric current.

The battery inside the GlucoWatch Biographer generates an electric field that pulls glucose molecules through the skin and then into the gel collection discs that are part of the AutoSensor, which is worn on the back of the Biographer next to the skin. The AutoSensor serves as the contact between the Biographer and your skin, conducting the electric current.

When current is applied, glucose molecules are pulled through the skin by charged molecules (positive and negative ions) and their surrounding medium, water. The ions migrate to the anode (+) and cathode (-) of the extracting electrodes that surround the gel collection discs in the AutoSensor. The glucose molecules are then collected in these discs for analysis.

Testing principle (continued)

The gel collection discs contain the enzyme glucose oxidase (GOx). As glucose enters the discs, it reacts with the GOx in the gel to form hydrogen peroxide. This reaction produces an electrochemical signal.

Biosensors surrounding the gel collection discs detect and measure this signal. The Biographer uses the calibration value to convert the signal to display your glucose levels.

The GlucoWatch Biographer contains a built-in audible alarm to notify you of potentially dangerous glucose conditions. This, as well as many other features of the system, can be programmed according to your individual needs.

Both the electronics and the programmable software are built into an application-specific integrated circuit (ASIC) chip contained within the Biographer. The electrodes used to extract and sense glucose are screen-printed on a translucent plastic sheet that is part of the AutoSensor. Silver-based electrodes are used for extraction and platinum electrodes are used for sensing.

Specifications

Power supply: 1 alkaline or rechargeable nickel metal hydride (Ni-MH) AAA battery

Battery life: 15 hours of use (12 hours of monitoring) per charge. Each Ni-MH battery can be charged approximately 500 times

Result range: 40 mg/dL to 400 mg/dL (2.2 mmol/L to 22.2 mmol/L). Out of range results will sound the alarm and the display will show <40 mg/dL or >400 mg/dL

Calibration range: 41 mg/dL to 279 mg/dL (2.3 mmol/L to 15.5 mmol/L)

Display type: Liquid crystal

Case: Drip-proof, IPX1 rating

Dimensions: 1.70" x 2.43" x .65"

Operating temperature range: 68°F–104°F (20°C–40°C)
skin temperature

Operating humidity range: 0%–90% relative humidity
(noncondensing)

Memory: Storage capacity of 4,000 data points, including
test results, event codes, or error messages
(oldest reading deleted first)

Current: 0.3 milliamps per square centimeter during
iontophoresis

Maximum applied voltage: 16 volts DC

Normal operating voltage range: 4–5 volts DC

Warnings and precautions

Warnings

- Do not ignore symptoms that may be due to low blood glucose or high blood glucose. The GlucoWatch® Biographer may not detect every instance that your glucose levels are too high or too low. If you have symptoms that do not match the Biographer readings, use your regular blood glucose meter to check the Biographer results.
- Do not change your treatment decisions based only on results from the Biographer. For example, some people use a blood glucose test result to help determine an insulin dose before each meal. This is often called a “sliding scale.” If you use a sliding scale, be sure to confirm the Biographer result with your regular blood glucose meter to make sure you take the right amount of insulin.

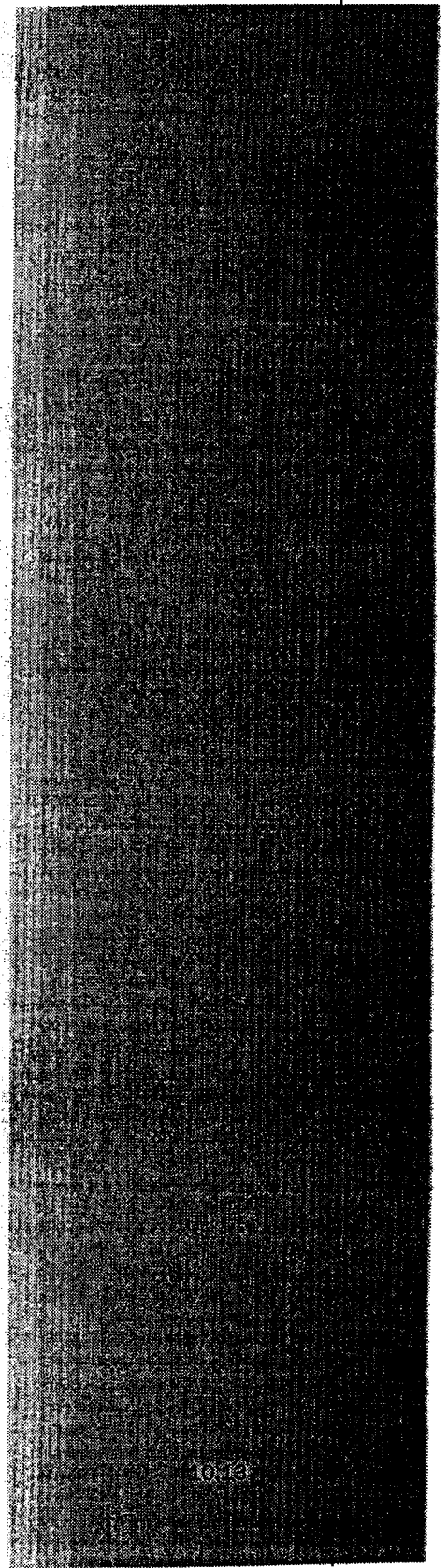
- Do not make fundamental changes in your treatment program without talking to your health care team. Serious illness or accidents may result.
- Remember that Biographer readings can differ from finger-stick test results. When it is time to make an important decision, the Biographer should not be used as a “substitute” for a finger-stick test. The Biographer must be used with finger-stick blood testing. Then you can make the best treatment decisions and reduce the chance of problems.

Precautions

- Always do the calibration step carefully. Entering the right number is important for accurate results. Follow the instructions for using your regular blood glucose meter. If you question the reading from your regular meter that you plan to use for calibration, repeat the blood glucose test.
- Be sure to set the Low Glucose Alert level 20 to 30 mg/dL above the blood glucose level that you want to make sure is detected. For example, if you want to detect a level of 60 mg/dL, you should set the Low Glucose Alert at 80 or 90 mg/dL. Otherwise, the GlucoWatch Biographer may miss some low blood glucose events and the alarm will not sound.

Warnings and precautions (continued)

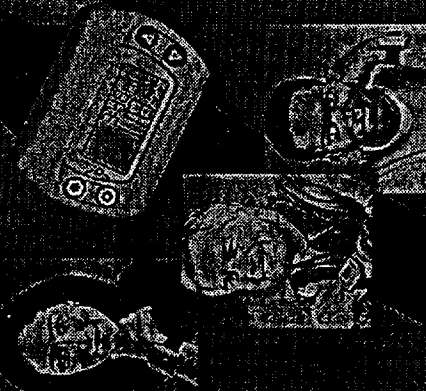
- Always check the last few readings in the Biographer memory to see the current trend in your glucose levels. One reading cannot tell you how fast your glucose levels are changing. If you question the Biographer results, confirm the Biographer readings with your regular blood glucose meter.
- Do not place the Biographer at any site where you have skin irritation left from a prior use. Also, do not place the Biographer on a scrape, cut, sunburn, or razor burn. Skin irritation may be worse than normal. Instead, use a different site on your arm.
- Do not use an expired AutoSensor. Check the expiration date on the package label before use.
- Do not share your Biographer with another person. This will prevent spreading infections.
- The Biographer readings may be affected by some hospital tests that use high electromagnetic equipment. This includes X rays and MRI tests.
- The medicines tolazamide or dopamine may affect Biographer readings. Tolazamide is a pill sometimes used for type 2 diabetes. Dopamine is given by injection for heart failure or shock. Ask a member of your health care team if you are uncertain if you are taking either of these medications.



GLUCOWATCH[®]

AUTOMATIC GLUCOSE BIOGRAPHER

QUICK REFERENCE GUIDE



For complete operating instructions, refer to the User's Guide

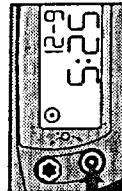
Running a System Check

Caution: You must insert a freshly charged battery in the battery compartment each time you put on your Biographer.



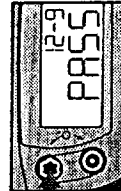
Step 1: Make sure the System Check Sensor is connected to your Biographer.

Step 1



Step 2: Press and hold the **Start** button until the **On Indicator** on the display appears and you hear 2 beeps.

Step 2



Step 3: Your Biographer will run the System Check. After about 10 seconds, the alarm will sound and the lower display will show **PASS** or **FAIL**. Press the **Change** button to confirm that you have heard the alarm.

Step 3

Step 4: If the display shows **PASS**, press the

Start button to return to the time and date display. If the display shows **FAIL**, the System Check Sensor may not have been properly seated. Reseat the System Check Sensor and run another System Check or call Technical Services at 1-866-GLWATCH.

Connecting the AutoSensor

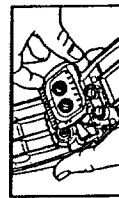
Step 1: Remove the System Check Sensor from the back of the Biographer if you have not already done so.



Step 2: Handling the AutoSensor by the ears, remove it from its pouch.

Step 2

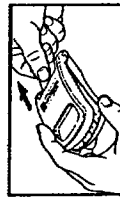
Caution: Check the gel collection discs for any spots or areas of different color. The gel collection discs should have a uniform but "cloudy" appearance. The gel collection discs are normally white to gray with a slight yellow tint. Do not use the AutoSensor if you see any spots or discoloration.



Step 3: Open the lid of the AutoSensor Press. Place the AutoSensor—adhesive pad side up—into the AutoSensor Press. There are 2 pegs in the

Press that fit through the holes in the AutoSensor.

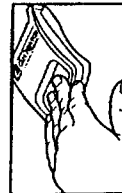
Step 3



Step 4: Gently bring the lid of the AutoSensor Press down. Holding the AutoSensor Press by its sides, remove protective liner 1 on the AutoSensor by pulling the tab labeled with alternating 1s and

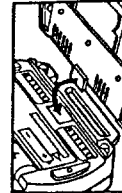
Step 4

arrows through the opening at the hinged end of the Press. Discard the liner.



Step 5: Firmly close the Press so that the lid and the base touch. Hold closed for 10 seconds.

Step 5



Step 7: Connect the AutoSensor to the Biographer by placing the tab on the AutoSensor into the slot on the back of the Biographer and holding the AutoSensor with your thumb and forefinger to snap it into place. A "click" lets you know the AutoSensor is properly seated.

Step 7

Caution: Do not skip these important directions. Be sure to use the AutoSensor Press. Skipping this step may cause faulty readings. Do not directly press the adhesive pad onto the electrodes with your fingers.

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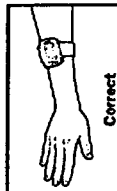
Putting on the Biographer

Step 1: Before putting on your Biographer, check to make sure that you have the correct watchband attached. Also, clean your skin with an alcohol swab and make sure to let your skin dry.

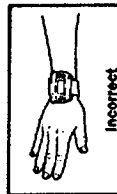
Step 2: Remove protective liner 2 from the AutoSensor by pulling the blue tab. Then place the Biographer onto the selected wearing site (on either your inner or outer forearm at least 2 inches from your wrist).



Step 2



Correct
Step 2 (continued)



Incorrect

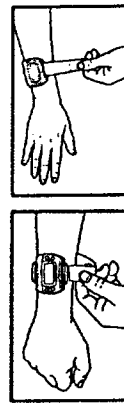
Step 3: Press firmly on the Biographer, so that the adhesive on the AutoSensor makes a firm bond with your skin.



Step 3

Caution: Remember, do not touch the sticky surface of the AutoSensor. Also, put on your GlucoWatch Biographer immediately; otherwise, the gel collection disc on the AutoSensor may dry out.

Step 4: Feed the strap through the D-ring and then pull the strap to tighten the band. Join the 2 Velcro® pieces together to fasten.



Step 4

Starting monitoring

The Biographer requires a 3-hour warm-up period before you can calibrate it and begin monitoring.

Step 1: Press and hold the Start button until you hear 2 beeps, signaling that the warm-up period has begun.



Step 1

Step 2: After the warm-up period, the alarm sounds to let you know that it's time to calibrate your Biographer.

2a: Press the Change button to shut off the alarm.

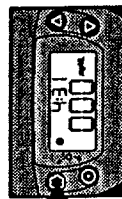
2b: You will see a flashing CAL message. Within the next 5 minutes, measure your blood glucose using a regular meter and enter your finger-stick reading into the Biographer.



Step 2b

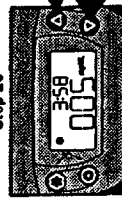
Note: When you calibrate your Biographer, your blood glucose value must be between 4.1 and 279 mg/dL.

2c: Press and hold the Change button until the CAL message is replaced by 3 zeros.



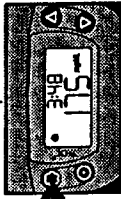
Step 2c

2d: Use the Up or Down button to replace the flashing zero with the number from your finger-stick test.



Step 2d

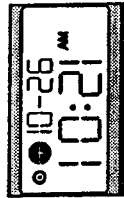
2e: Press the Change button so the next zero flashes and repeat until all numbers are entered (from right to left).



Step 2e

2f: Press the Start button to confirm the calibration. Press the Start button again to return to the time and date display.

Step 3: Over the next 15 minutes, the Biographer completes an internal measurement matched to your finger-stick reading. When this internal measurement is completed, the Countdown timer will appear on the display. Automatic glucose monitoring is now under way.



Step 3

Checking earlier readings

Press the Up button to scroll backward through your glucose readings. Press and hold the Up button to move quickly through memory.

Stopping monitoring

Press both the Start button and the Change button at the same time. The On indicator and the Countdown timer will disappear from the upper display. OFF alternating with STOP will appear in the lower display and an alarm will sound. Press the Change button to stop the alarm. Press the Start button to return to the time and date display.

When you stop glucose monitoring, you must replace the used AutoSensor before you can monitor again!

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References: 1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329:977-986. 2. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care.* 2000;23:S32-S42.

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